Docket No.: 022290.0116C1US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Valerie Legrand et al.

Application No.: 10/826,690 | Confirmation No.: 9585

Filed: April 19, 2004 | Art Unit: 1618

For: MICROPARTICULATE ORAL GALENICAL FORM FOR THE DELAYED AND CONTROLLED RELEASE OF PHARMACEUTICAL ACTIVE PRINCIPLES | Examiner: L. H. Schlientz

PETITION FOR UNINTENTIONALLY DELAYED CLAIM FOR PRIORITY UNDER 37 CFR § 1.78(a)(3)

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified application has an incomplete priority claim. Paragraph [0001] of the current specification reads "This application is a continuation-in-part of Application No. _____, which is the National Stage of International Application No. PCT/FR02/03443, filed Oct. 9, 2002, and claims the benefit of FR01/12999, filed Oct. 9, 2001, each of which is incorporated herein by reference."

When this application was filed on April 19, 2004, the application number of the parent application, filed April 7, 2004, was unavailable. As such, the application number of the parent application was not provided at the time of filing.

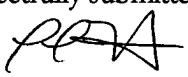
As per 37 CFR §1.78(a)(3), we therefore submit a statement that the entire delay between the date the claim was due under paragraph 37 CFR (a)(2)(ii) and the date the claim filed is unintentional. It is submitted, therefore, that on the basis described above the priority claim should be held to be inadvertent and the enclosed Amendment and Response should be entered.

As amended, Paragraph [0001] will read, "This application is a Continuation-in-Part of Application No. 10/492,129, filed July 19, 2004. U.S. Application No. 10/492,129 is the National Stage of International Application No. PCT/FR02/03443, filed Oct. 9, 2002, which is incorporated therein by reference, and claims the benefit of FR01/12999, filed Oct. 9, 2001, which is incorporated herein by reference."

Please charge our Credit Card in the amount of $1,410.00 covering the fee set forth in 37 CFR 1.17(t). Credit Card Payment Form SB-2038, with a signature from an authorized cardholder, is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2228, under Order No. 022290.0116C1US.

Dated: January 28, 2008

Respectfully submitted,

By 

Lacy L. Kolo
Registration No.: 55,340
PATTON BOGGS LLP
8484 Westpark Drive, 9th Floor
McLean, Virginia 22102
(703) 744-8000
(703) 744-8001 (Fax)
Attorney for Applicant

Dynasan

PRODUCT INFORMATION

26.13.060e/04.00

DYNASAN® 114, 116, 118
Microcrystalline Triglycerides

Description
DYNASAN® microcrystalline triglycerides are glycerin esters of selected saturated, even-numbered and unbranched fatty acids of natural origin. They are free from antioxidants and other stabilizers.

$R\text{-}CH_2\text{-}CH(R)\text{-}CH_2\text{-}R$
R = either C10-, C12-, C14-, C16- or C18-residues of fatty acids

Official Descriptions
JSCI[1] (Japan):	DYNASAN® 114 - Glyceryl Trimyristate
JCIC[2] (Japan):	DYNASAN® 116 - Glyceryl Tripalmitate
JCIC (Japan):	DYNASAN® 118 - Glyceryl Tristearate
INCI Name:	DYNASAN® 114 - Trimyristin
INCI Name:	DYNASAN® 116 - Tripalmitin
INCI Name:	DYNASAN® 118 - Tristearin
CFR[3] (USA):	DYNASAN® 118 - Glyceryl Tristearate (21, CFR §172.811)

Characteristic Values

Tests	Method	Unit	DYNASAN® 114	DYNASAN® 116	DYNASAN® 118
Acid value*	EP[4] 2.5.1	mg KOH/g	max. 3	max. 3	max. 3
Saponification value*	DGF[5] C-V2	mg KOH/g	229 - 238	205 - 215	186 - 192
Hydroxyl value	DGF C-V 17a	mg KOH/g	max. 10	max. 10	max 10
Melting range	EP 2.2.14	°C	55 - 58**	61 - 65***	70 - 73***
Unsaponifiable matter	EP 2.5.7	%	max. 0.5	max. 0.5	max. 1

* Included in Certificate of Analysis
** Mettler FP 81
*** DSC

Besides these product-specific characteristic values, the products are distinguished by their stability against oxidation. Their peroxide values are 3 max., and their water content is 0.1 % max.

Characteristics
If the individual grades of DYNASAN® are rapidly cooled after melting, glassy, amorphous masses are initially formed, which change upon standing into crystalline modifications having volume expansion. The stable E-modification has a very sharp melting point and a triclinic structure.

SASOL Germany GmbH
Oleochemicals
Arthur-Imhausen-Str. 92, D-58453 Witten
Phone: +49 (0)2302/925-251 Fax: +49 (0)2302/925-358
U.S.: SASOL North America Inc., 900 Threadneedle, Houston, TX 77079
Phone: 201-666-9918 Fax: 201-666-9623

Solubility

DYNASAN® 114 is slightly soluble in n-hexane and diethyl ether and has very low solubility in ethanol.
DYNASAN® 116 and 118 are slightly soluble in n-hexane, as well as diethyl ether and ethanol.
All types are virtually insoluble in water.

Applications

DYNASAN® microcrystalline triglycerides are used in the cosmetic and pharmaceutical industries as adjuvants in the following preparations:

- In tablets as lubricants having a very small influence on disintegration. (See table below.)
- In suppositories, vaginal ovula and pharmaceutical/cosmetic sticks as crystallization accelerators and seeding agents to improve the solidification process.
- In ointments, creams and lotions as body-imparting and structure-forming components.

Toxicology

The LD_{50} value in the rat of all DYNASAN® types is greater than 5 g/kg body weight.

Influence of the lubricant on the disintegration of tablets

Base Substance	Lubricant	Concentration (%)	Pressure (mPa·s)	Disintegration (sec.)
Lactose	Mg-stearate	0.25	195	600
Lactose	Sterotex®	4	221	250
Lactose	Precirol®	2	211	210
Lactose	DYNASAN® 114	1	206	106
Lactose	DYNASAN® 116	1	202	101
Lactose	DYNASAN® 118	1	228	111

A. Stamm, Sci. Techn. Pharm. 9 (1), 471 - 478 (1980)

Delivery Form and Packaging

DYNASAN® 114, 118: Powder, 25 kg net cartons
DYNASAN® 116: Flakes, 25 kg net bags

Storage and Shelf Life

DYNASAN® microcrystalline triglycerides should be stored in tightly closed containers, protected from light and moisture. Under these conditions, the shelf life of the products is at least two years.

Please refer to SASOL Material Safety Data Sheets for specific, complete information regarding the safe handling, health and environmental effects for these products.

1) JCIC = Japanese Cosmetic Ingredients Codex
2) JSCI = Japanese Standards of Cosmetic Ingredients
3) CFR = Code of Federal Regulations
4) EP = European Pharmacopoeia
5) DGF = Deutsche Gesellschaft für Fettwissenschaft

Cutina

nutrition&health

Product Range & Applications – Cognis PharmaLine™

PharmaLine™ is our premium range of high-quality, oleochemical-derived pharma-grade excipients. **PharmaLine™ benefits:**

- Analysis according to original current Pharmacopeia methods (EP, USP/NF and optionally JP/JPE) performed on each batch (multicompendial status)
- Manufacturing according to IPEC – PQG GMP guidelines (cleaning procedures, documentation, traceability); IPEC – PQG GMP conformity declaration
- Extensive purity data determined for each batch (microbiology, aflatoxins, heavy metals, pesticides)
- Proprietary service, e.g. US Drug Master Files (type IV), certificates, audits etc.

Cognis high-quality PharmaLine™ excipients can be used for topical, oral, parenteral and other applications as tableting aids, solubilizers and solvents, consistency factors, emulsifiers, emollients, cream bases, suppository masses, moisturizers etc. in solid, semi-solid and liquid pharmaceutical dosage forms.

Pharma-Grade Excipients

Monographic Name EP	Monographic Name USP/NF	Monographic Name JP/JPE	US DMF No.	Cognis Product Name	Applications	Single Package	Full Pallet Size
-	Myristyl Alcohol	Myristyl Alcohol	-	Speziol C14 Pharma	Consistency Factor	20 kg	420 kg
Castor Oil Hydrogenated	Hydrogenated Castor Oil	Hydrogenated Oil	16502	Cutina HR Pharma	Tableting Aid	20 kg	420 kg
Cetostearyl Alcohol	Cetostearyl Alcohol	Cetostearyl Alcohol	17080	Speziol C16/18 Pharma	Consistency Factor, Tableting Aid	25 kg	450 kg
Cetostearyl Isononanoate	-	-	16821	Cetiol SN Pharma	Emollient, Solvent	175 kg	700 kg
Cetostearylalcohol (Type A), Emulsifying	-	Cetostearylalcohol and Sodium Cetostearyl Sulfate Mixture	16823	Lanette N Pharma	Selfemulsifying Cream Base	20 kg	420 kg
Cetyl Alcohol	Cetyl Alcohol	Cetanol	17082	Speziol C16 Pharma	Consistency Factor, Tableting Aid	25 kg	450 kg
Cetyl Palmitate 15	-	Cetyl Palmitate	16501	Cutina CP Pharma	Emollient	20 kg	420 kg
Cocoyl Caprylocaprate	-	-	16496	Cetiol LC Pharma	Emollient, Solvent	800 kg	800 kg
Decyl Oleate	-	Decyl Oleate	16500	Cetiol V Pharma	Emollient, Solvent	850 kg	700 kg

cognis
we know how

Thank you for your request. Here are the latest results from the TARR web server.

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Serial Number: 72283780 Assignment Information Trademark Document Retrieval

Registration Number: 865575

Mark (words only): CUTINA

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 1999-06-10

Filing Date: 1967-10-31

Transformed into a National Application: No

Registration Date: 1969-03-04

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 900 -File Repository (Franconia)

Date In Location: 2001-12-05

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. COGNIS DEUTSCHLAND GMBH & CO.KG

Address:
COGNIS DEUTSCHLAND GMBH & CO.KG
HENKELSTRASSE 67 R - INTELLECTUAL PROPERTY / TRADEMARKS
DUESSELDORF D-40589
Fed Rep Germany
Legal Entity Type: Corporation
State or Country of Incorporation: Fed Rep Germany

GOODS AND/OR SERVICES

U.S. Class: 006 (International Class 001)
Class Status: Active
ORGANIC CHEMICAL COMPOSITIONS FOR USE IN THE MANUFACTURE OF COSMETIC CREAMS AND OINTMENTS
No Filing Basis Claimed

First Use Date: (DATE NOT AVAILABLE)
First Use in Commerce Date: (DATE NOT AVAILABLE)

ADDITIONAL INFORMATION

Foreign Registration Number: 641828
Foreign Registration Date: 1950-10-16
Country: Fed Rep Germany

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2006-03-29 - TEAS Change Of Correspondence Received

2003-09-26 - TEAS Change Of Correspondence Received

1999-06-10 - Second renewal 10 year

1999-03-04 - Section 9 filed/check record for Section 8

1990-01-09 - First renewal 10 year

1989-11-03 - Response received for Post Registration action

1989-05-11 - Post Registration action mailed - Section 9

1989-03-10 - Section 9 filed/check record for Section 8

ATTORNEY/CORRESPONDENT INFORMATION

Correspondent
John F. Daniels

Dub

DUB OPC

▸ **General Information**

Trade	DUB
Grade	DUB OPC
Producer	Stearinerie Dubois
Chemical Name	
CAS Number	84929-27-1

Appearance	Powder, fine
Color	Beige
Odor	Characteristic

CTFA/INCI Name	Vitis vinifera (Grape) seed extract
EINECS	284-511-6

▸ **Active Ingredient**

- anti-ageing
- antioxidant/ antipollution
-

▸ **Origin/Nature**

- fruits extracts
- polyphenols/ flavonoids

▸ **End Application**

- skin care (facial care, facial cleansing, body care, baby care) >> facial care >> anti-ageing preparations
- sun care (sun protection, after-sun & self-tanning)

▸ **Comments**

From Special Chem Database
www.specialchem4cosmetics.com
13/4/07

Grape seed extract. Contains natural antioxidants and anti-free radicals scavengers. Used in sun care and anti-ageing products.

Quantitative Properties

- Density: > 0.35
- Water content: < 7 %
- Total polyphenols content: > 95 %
- Procyanidins: > 40 %
- Antiradical power DPPH: < 2 mg/L
- Lead content: < 5 ppm
- Arsenic content: < 3 ppm
- Mercury content: < 1 ppm

Castorwax

Castorwax®
Technical Data Sheet

Product Identification

Castorwax® is a wax like compound obtained by the controlled hydrogenation of pure castor oil. The principle constituent is glycerol tri-(12-hydroxystearate), also known as opalwax. Castorwax® is a hard, brittle, high melting point wax that is insoluble in most organic solvents but is highly compatible with most resins and waxes.

Physical Properties

Property	Value
Acid Value	1
Density, lbs./gal, 25˚C	8.51
Fire Point, COC, ˚F	635
Flash Point, COC, ˚F	600
Form	White flakes
Hydroxyl Value	165
Iodine Value	3
Melt Point, °C	87
Melt Viscosity, Poise @ 200°F	0.24
Molecular Weight	934
Refractive Index	1.4620
Saponification Value	180
Specific Gravity, 25˚C/25˚C	1.023
Volume Resistivity @ 100°C	8.2×10^{10}
Dielectric Constant @ 1Kc@45°C	12.7
Dielectric Constant @ 1Kc@100°C	3.77

Applications

- Metal drawing lubricants
- Processing aid for rubber and plastics
- Cosmetics and toiletries
- Antiperspirant sticks
- Thixatrope
- Tableting – controlled release binder

For toxicity or regulatory information please consult the Material Safety Data Sheet.

Vertellus Performance Materials Inc., 2110 High Point Road, Greensboro, NC 27403 USA
USA Tel: 800-227-2436 **USA Fax:** 336-854-4058 **USA Email:** VPM-TechServices@vertellus.com
Web: www.vertellus.com

Revised November, 2006

Products

Product Name: CASTORWAX®

Technical Data Sheet

Title	Language
CASTORWAX®	English

MSDS

Title	Language
CASTORWAX®	English

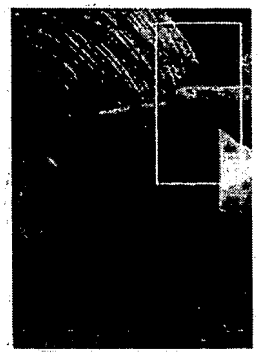
Contact Us

Need any additional information/assistance? Please Email Or Call Us

Croduret

Personal Care
Europe

Product summary



Croduret 7 Special
Fully saturated castor oil derivative widely used in skin care products

Details:

INCI:	PEG-7 Hydrogenated Castor Oil
EINECS:	Polymer

Properties:

Chemical group:	Surfactants - nonionic - ethoxylated vegetable oils
Appearance:	White to pale yellow viscous liquid
Molecular weight:	-
HLB:	5.0

Request more information

Benefits / Properties:
- Primary W/O emulsifier
- O/W coemulsifier
- Emollient
- Lubricant
- Excellent oxidative stability

Applications:
- Skin care creams and lotions
- Sun care
- Baby products
- Detergent cleansers
- Bath products

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- Functional specialities
- Polymer additives
- Crop care

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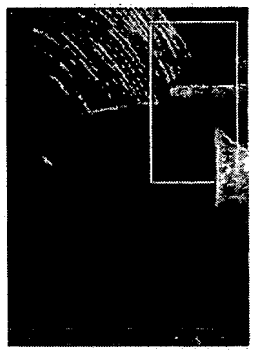
Product summary



Croduret 60
Fully saturated castor oil derivative widely used in skin and hair care products

Details:

INCI:	PEG-60 Hydrogenated Castor Oil
EINECS:	Polymer

Properties:

Chemical group:	Surfactants - nonionic - ethoxylated vegetable oils
Appearance:	White waxy solid
Molecular weight:	-
HLB:	14.7

Request more information

Benefits / Properties:

- O/W emulsifier
- Emollient
- Superfatting agent
- Solubiliser
- Excellent oxidative stability

Applications:

- Skin care creams and lotions
- Sun care
- Baby products
- Detergent cleansers
- Bath products
- Hair care products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- Polymer additives
- Crop care

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Product summary

Croduret 50 Special
Fully saturated castor oil derivative widely used in skin and hair care products

Details:

INCI:	PEG-40/45 Hydrogenated Castor Oil
EINECS:	Polymer

Properties:

Chemical group:	Surfactants - nonionic - ethoxylated vegetable oils
Appearance:	White paste liquifying at approx 30°C
Molecular weight:	-
HLB:	14.1

Request more information

Benefits / Properties:

- Excellent solubiliser for perfumes and essential oils
- O/W emulsifier
- Emollient
- Superfatting agent
- Excellent oxidative stability

Applications:

- Skin care creams and lotions
- Sun care
- Baby products
- Detergent cleansers
- Bath products
- Hair care products


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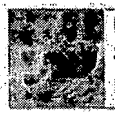
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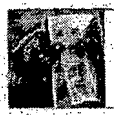
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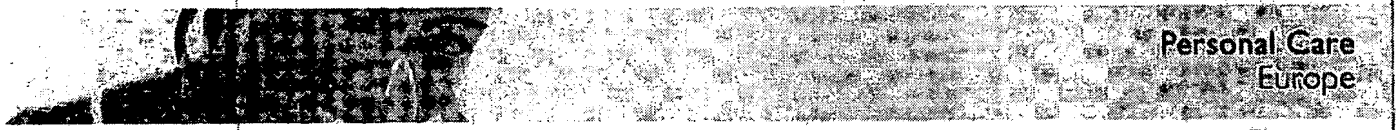

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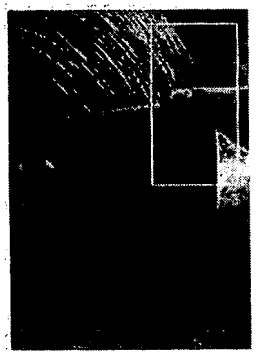

Croduret 40LD
Fully saturated castor oil derivative widely used in skin and hair care products

Details:

INCI:	PEG-40 Hydrogenated Castor Oil
EINECS:	Polymer

Properties:

Chemical group:	Surfactants - nonionic - ethoxylated vegetable oils
Appearance:	White to off-white semi-solid
Molecular weight:	-
HLB:	13.0

Request more information

Benefits / Properties:
- O/W emulsifier
- W/O coemulsifier
- Solubiliser for perfumes and essential oils
- Emollient
- Superfatting agent
- Lubricant
- Excellent oxidative stability

Applications:
- Skin care creams and lotions
- Sun care
- Baby products
- Detergent cleansers
- Bath products
- Hair care products


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Compritol

Int. Cl.: 5

Prior U.S. Cl.: 18

United States Patent and Trademark Office

Reg. No. 1,291,754

Registered Aug. 28, 1984

TRADEMARK

Principal Register

COMPRITOL

Etablissements Gattefosse (France corporation)
36, Chemin de Genas
Saint-Priest (Rhone), France

For: ADDITIVES FOR PHARMACEUTICAL TABLETS IN THE NATURE OF AN EXCIPIENT HAVING BINDING, LUBRICATING, DISINTEGRATING AND SUSTAINED RELEASE PROPERTIES, in CLASS 5 (U.S. Cl. 18).

Owner of France Reg. No. 1,154,977, dated Nov. 18, 1980, expires Nov. 18, 1990.

Ser. No. 391,005, filed Sep. 28, 1982.

EVAN J. KRAME, Examining Attorney

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Serial Number: 73391005 Assignment Information Trademark Document Retrieval

Registration Number: 1291754

Mark (words only): COMPRITOL

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2004-03-26

Filing Date: 1982-09-28

Transformed into a National Application: No

Registration Date: 1984-08-28

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 900 -File Repository (Franconia)

Date In Location: 2004-03-29

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. GATTEFOSSE S.A.

Address:
GATTEFOSSE S.A.
36 CHEMIN DE GENAS
69800 SAINT-PRIEST
France
Legal Entity Type: Joint Stock Company
State or Country Where Organized: France

GOODS AND/OR SERVICES

International Class: 005
Class Status: Active
Additives for Pharmaceutical Tablets in the Nature of an Excipient Having Binding, Lubricating, Disintegrating and Sustained Release Properties
No Filing Basis Claimed

First Use Date: (DATE NOT AVAILABLE)
First Use in Commerce Date: (DATE NOT AVAILABLE)

ADDITIONAL INFORMATION

Foreign Registration Number: 1,154,977
Foreign Registration Date: 1980-11-18
Country: France
Foreign Expiration Date: 1990-11-18

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2004-03-26 - First renewal 10 year

2004-03-26 - Section 8 (10-year) accepted/ Section 9 granted

2004-02-13 - Combined Section 8 (10-year)/Section 9 filed

1989-11-14 - Section 8 (6-year) accepted & Section 15 acknowledged

1989-09-14 - Section 8 (6-year) and Section 15 Filed

1984-08-28 - Registered - Principal Register

1984-06-05 - Published for opposition

1984-04-11 - Notice of publication

1984-03-02 - Approved for Pub - Principal Register (Initial exam)

1984-02-10 - Assigned To Examiner

1984-01-13 - Communication received from applicant

1983-07-15 - Non-final action mailed

1983-06-22 - Assigned To Examiner

ATTORNEY/CORRESPONDENT INFORMATION

Correspondent
ROGER W. PARKHURST,
PARKHURST & WENDEL, LLP
1421 PRINCE ST, STE 210
ALEXANDRIA, VA 22314-2805

Domestic Representative
ARNOLD, WHITE & DURKEE

Purchase psul (2006) 23: 417-33.

Polymorphic behaviour of Compritol(R)888 ATO as bulk lipid and as SLN and NLC.

EB Souto, W Mehnert, RH Müller
Department of Pharmaceutics, Biopharmaceutics and Biotechnology, Free University of Berlin, Berlin, Germany.

Compritol(R)888 ATO (glycerol behenate) is widely used as a pharmaceutical excipient in the field of solid dosage forms due to its lubricating properties. It is an amphiphilic material with a high melting point (approximately 70 degrees C) and,

Printout from www.nano-biology.net 12/5/07

therefore, it can also be used to prepare aqueous colloidal dispersions. The aim of this paper is to study the suitability of Compritol(R)888 ATO for the production of solid lipid nanoparticles (SLN) and nanostructured lipid carriers (NLC) for the entrapment of a lipophilic model drug. This study assesses the crystalline structure of the bulk lipid, as well as the changes that occur in its crystal lattice with the addition of 'impurities', such as oil (alpha-tocopherol) and drug (ketoconazole), using DSC and X-ray diffraction analysis before and after thermal stress. Aqueous SLN and NLC dispersions were produced using an appropriate surfactant/co-surfactant system and their physicochemical stability was assessed by PCS, LD, DSC and by WAXS. It was found that the crystalline lattice of Compritol(R)888 ATO is composed of very small amounts of the unstable alpha polymorphic form characteristic of triacylglycerols, which disappears after thermal stress of bulk lipid. Mixing oils and drug molecules which are soluble in this lipid decreased its lattice organization and, thus, was revealed to be suitable for production of lipid nanoparticles containing ketoconazole. However, particle growth could not be avoided during shelf life.

Browse nanomedicine articles via key phrases:

thermal, DSC, lipid, compritolr888 ato, NLC dispersions, surfactant/co-surfactant, Aqueous SLN, lipid nanoparticles, particle growth, physicochemical, crystalline lattice, Mixing oils, drug, disappears, X-ray diffraction, unstable alpha polymorphic, lattice, oil alpha-tocopherol, amphiphilic, melting, lubricating, solid, pharmaceutical excipient, field, suitability, solid lipid nanoparticles sln, crystalline structure, crystal lattice, assesses, entrapment, nanostructured lipid carriers nlc, compritolr888 ato glycerol behenate,

Related nanomedicine articles:

Polymorphic behaviour of Compritol(R)888 ATO as bulk lipid and as SLN and NLC. **(2006)** *psul*

Control of the electrical conductivity of composites of antimony doped tin oxide (ATO) nanoparticles and acrylate by grafting of 3-methacryloxypropyltrimethoxysilane (MPS). **(2006)** *J Colloid Interface Sci*

Solid lipid nanoparticles incorporated in dextran hydrogels: A new drug delivery system for oral formulations. **(2006)** *Int J Pharm*

Physicochemical investigations on the structure of drug-free and drug-loaded solid lipid nanoparticles (SLN) by means of DSC and 1H NMR. **(2005)** *Pharmazie*

Lipid nanoparticles for alkyl lysophospholipid edelfosine encapsulation: Development and in vitro characterization. **(2007)** *Eur J Pharm Biopharm*

Further characterization of theobroma oil-beeswax admixtures as lipid matrices for improved drug delivery systems. **(2006)** *Eur J Pharm Biopharm*

Characterization of indomethacin-loaded lipid nanoparticles by differential scanning calorimetry. **(2005)** *Int J Pharm*

Solvent injection as a new approach for manufacturing lipid nanoparticles--evaluation of the method and process parameters. **(2003)** *Eur J Pharm Biopharm*

Artemisia arborescens L essential oil-loaded solid lipid nanoparticles for potential agricultural application: preparation and characterization. **(2006)** *AAPS PharmSciTech*

Solid lipid nanoparticles as carriers of hydrocortisone and progesterone complexes with beta-cyclodextrins. **(1999)** *Int J Pharm*

Enter up to 3 email addresses:

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Sterotex

United States Patent Office 766,603
Registered Mar. 17, 1964

PRINCIPAL REGISTER
Trademark

Ser. No. 171,089, filed June 17, 1963

STEROTEX

The Capital City Products Company (Delaware corporation)
525 W. 1st Ave.
Columbus, Ohio

For: POWDERED VEGETABLE STEARINE USED AS A LUBRICANT IN THE COMPRESSING AND EXTRUDING OF PHARMACEUTICAL TABLETS, POWDERED METAL PRODUCTS, CATALYSTS, CHEMICALS AND CERAMIC PARTS, in CLASS 15.
First use June 1, 1951; in commerce June 1, 1951.
Owner of Reg. No. 520,636.

Thank you for your request. Here are the latest results from the TARR web server.

This page was generated by the TARR system on 2007-12-06 15:40:07 ET

Serial Number: 72171089 Assignment Information Trademark Document Retrieval

Registration Number: 766603

Mark (words only): STEROTEX

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2004-05-27

Filing Date: 1963-06-17

Transformed into a National Application: No

Registration Date: 1964-03-17

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 900 -File Repository (Franconia)

Date In Location: 2004-05-28

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. ABITEC CORPORATION

Address:
ABITEC CORPORATION
501 WEST 1ST AVENUE
COLUMBUS, OH 43215
United States
Legal Entity Type: Corporation
State or Country of Incorporation: Delaware

GOODS AND/OR SERVICES

U.S. Class: 015 (International Class 004)
Class Status: Active
Powdered Vegetable Stearine Used as a Lubricant in the Compressing and Extruding of Pharmaceutical Tablets, Powdered Metal Products, Catalysts, Chemicals and Ceramic Parts
Basis: 1(a)
First Use Date: 1951-06-01
First Use in Commerce Date: 1951-06-01

ADDITIONAL INFORMATION

Prior Registration Number(s):
520636

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2004-05-27 - Second renewal 10 year

2004-05-27 - Section 8 (10-year) accepted/ Section 9 granted

2004-03-23 - PAPER RECEIVED

2004-03-15 - Combined Section 8 (10-year)/Section 9 filed

2003-12-08 - TEAS Change Of Correspondence Received

2003-10-27 - TEAS Change Of Correspondence Received

1984-03-17 - First renewal

ATTORNEY/CORRESPONDENT INFORMATION

Correspondent
LAING P. AKERS
SQUIRE, SANDERS & DEMPSEY L.L.P.
1300 HUNTINGTON CENTER
41 SOUTH HIGH STREET
COLUMBUS, OH 43215-6197

STEROTEX® HM, NF

ABITEC An AEP Industries Company

CAS Number: 8016-70-4

Meets the requirements of the United States Pharmacopeia/National Formulary (USP/NF) monograph for *Hydrogenated Vegetable Oil, Type 1*, the British Pharmacopoeia (BP) monograph for *Hydrogenated Vegetable Oil* and the European Pharmacopoeia (EP) general monograph for *Vegetable Fatty Oils.*

Synonyms:

Hydrogenated Soybean Oil

Product Type:

Sterotex HM, NF powders are widely used as lubricants in tablet manufacturing in the pharmaceutical industries, the food supplement industries, and in compacting and compounding processes in the catalyst, ceramic and powder metallurgy fields. **Sterotex HM, NF** lubricant powders are derived from natural vegetable oils that are refined and deodorized and is produced according to Kosher requirements. They are neutral organic esters (triglycerides) that are low in ash content. **Sterotex HM, NF** conforms to the United States Pharmacopeia/ National Formulary (USP/NF) monograph for *Hydrogenated Vegetable Oil, Type I*, the British Pharmacopoeia (BP) monograph for *Hydrogenated Vegetable Oil* and the European Pharmacopoeia (EP) general monograph for *Vegetable Fatty Oils.*

Specifications:

Specification	Limit	Reference Test Method
Color, Lovibond (Red)	3.0 max.	[1]AOCS Cc 13b-45
Acid Value	4.0 max.	[2]NF / [3]BP
Identification	Pass/Fail	BP
Iodine Value	5.0 max.	NF / BP
Loss on Drying	0.1%	NF / BP
Melting Point	67-69°C (153-157°F)	NF / BP
Saponification Value	175-200	NF / BP

Compliance is Pass/Fail for the following test parameters outlined per NF, BP or ABITEC specifications:

Heavy Metals	0.001%	NF / BP
OVI (Organic Volatile Impurities)	Pass/Fail	NF
Unsaponifiable Matter	0.8% max.	NF / BP
Characteristics	Pass/Fail	BP
Sieve Analysis:		ABITEC Method
Particle Size	95% minimum through 100 mesh	
Particle Size	99% minimum through 40 mesh	

[1]AOCS: American Oil Chemists' Society [2]USP/NF United States Pharmacopeia/National Formulary [3]BP: British Pharmacopoeia

30 West First Avenue, Columbus, Ohio 43215 • tel 614-429-6464 • fax 614-299-8279 • email sales@abitec.com • www.abitec.com

Regulatory:

Meets the requirements of the current United States Pharmacopeia/National Formulary (USP/NF) monograph for *Hydrogenated Vegetable Oil, Type 1*, the British Pharmacopoeia (BP) monograph for *Hydrogenated Vegetable Oil* and the European Pharmacopoeia (EP) general monograph *for Vegetable Fatty Oils*.

Pharmaceutical Applications:

- Tablet Lubricant
- Sustained Release Applications
- Binder

Shelf Life:

Retest and re-qualify one year from the date of manufacture.

Storage:

Store in a closed container in a dry location at 65-70° F.

Standard Package:

50 lb. (22.7 kg.) cartons
75 lb. (34 kg.) drums

501 West First Avenue, Columbus, Ohio 43215 • tel: 614-429-6464 • fax: 614-299-8279 • email: sales@abitecorp.com • www.abitecorp.com

STEROTEX® K, NF

ABITEC An ADF Ingredients Company

CAS Number: 8016-70-4* & 8001-78-3*

Meets the requirements of the United States Pharmacopeia/National Formulary monograph for *Hydrogenated Vegetable Oil, Type 1.*

Synonyms:

Hydrogenated Vegetable Oil
Hydrogenated Soybean Oil and Castor Wax
Vegetable Stearine

Product Type:

Sterotex K, NF powders are prepared from vegetable oils that are refined, deodorized, hydrogenated and spray chilled to fine powders. They are neutral esters (triglycerides) which are low in ash content. **Sterotex K, NF** powders are widely used as lubricants in tablet manufacturing in the pharmaceutical industries and in food supplements. They are also used in compacting and compounding processes in the catalyst, ceramic and powder metallurgy fields. **Sterotex K, NF** conforms to the USP/NF monograph for *Hydrogenated Vegetable Oil, Type I* and is produced according to Kosher requirements.

Specifications:

Specification	Limit	Reference Test Method
Color, Lovibond (Red)	4.0 max.	[1]AOCS Cc 13b-45
Acid Value	4.0 max.	[2]NF
Iodine Value	5.0 max.	NF
Loss on Drying	0.1%	NF
Melting Point	81-84°C (178-183°F)	NF
Saponification Value	175-200	NF

Compliance is Pass/Fail for the following test parameters outlined per USP/NF or ABITEC specifications:

Heavy Metals (Method II)	0.001%	NF
OVI (Organic Volatile Impurities)	Pass/Fail	NF
Unsaponifiable Matter	0.8% max.	NF
Sieve Analysis:		ABITEC Method
Particle Size	95% minimum through 100 mesh	
Particle Size	99% minimum through 40 mesh	

[1]AOCS: American Oil Chemists' Society [2]USP/NF United States Pharmacopeia/National Formulary

501 West First Avenue, Columbus, Ohio 43215 • tel: 614-429-6464 • fax: 614-299-8279 • email: sales@abiteccorp.com • www.abitecorp.com

Regulatory:

Meets the requirements of the current United States Pharmacopeia/National Formulary (USP/NF) monograph for *Hydrogenated Vegetable Oil, Type 1.*

Pharmaceutical Applications:

- Tablet Lubricant
- Sustained Release Applications
- Binder

Shelf Life:

Retest and re-qualify one year from the date of manufacture.

Storage:

Store in a closed container in a dry location at 65-70° F.

Standard Package:

50 lb. (22.7 kg.) cartons
75 lb. (34 kg.) drums

5757 Tussing Road, Columbus, Ohio 43215 • tel: 614-428-6484 • fax: 614-299-8279 • email: sales@abitecorp.com • www.abitecorp.com

Lubritab

Int. Cl.: 5

Prior U.S. Cl.: 6

United States Patent and Trademark Office

Reg. No. 1,174,778

Registered Oct. 27, 1981

TRADEMARK
Principal Register

LUBRITAB

Edward Mendell Co., Inc. (New York corporation)
Rte. 52
Carmel, N.Y. 10521

For: HYDROGENATED VEGETABLE OILS FOR USE AS A DRY LUBRICANT OR AUXILIARY BINDER IN THE MANUFACTURE OF PHARMACEUTICAL TABLETS, in CLASS 5 (U.S. Cl. 6).

First use Mar. 1976; in commerce Mar. 1976.

Ser. No. 250,157, filed Feb. 14, 1980.

ROY H. NEILSON, Primary Examiner

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This page was generated by the TARR system on 2007-12-06 15:43:45 ET

Serial Number: 73250157 Assignment Information Trademark Document Retrieval

Registration Number: 1174778

Mark (words only): LUBRITAB

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2002-01-25

Filing Date: 1980-02-14

Transformed into a National Application: No

Registration Date: 1981-10-27

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 900 -File Repository (Franconia)

Date In Location: 2002-01-29

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. PENWEST PHARMACEUTICALS CO.

Address:
PENWEST PHARMACEUTICALS CO.
2981 ROUTE 21
PATTERSON, NJ 12563
United States
Legal Entity Type: Corporation
State or Country of Incorporation: Washington

GOODS AND/OR SERVICES

International Class: 005
Class Status: Active
Hydrogenated Vegetable Oils for Use as a Dry Lubricant or Auxiliary Binder in the Manufacture of Pharmaceutical Tablets
Basis: 1(a)
First Use Date: 1976-03-00
First Use in Commerce Date: 1976-03-00

ADDITIONAL INFORMATION

(NOT AVAILABLE)

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2002-01-25 - First renewal 10 year

2002-01-25 - Section 8 (10-year) accepted/ Section 9 granted

2001-10-29 - Combined Section 8 (10-year)/Section 9 filed

1987-04-27 - Section 8 (6-year) accepted & Section 15 acknowledged

1986-12-04 - Section 8 (6-year) and Section 15 Filed

1981-10-27 - Registered - Principal Register

1981-08-04 - Published for opposition

ATTORNEY/CORRESPONDENT INFORMATION

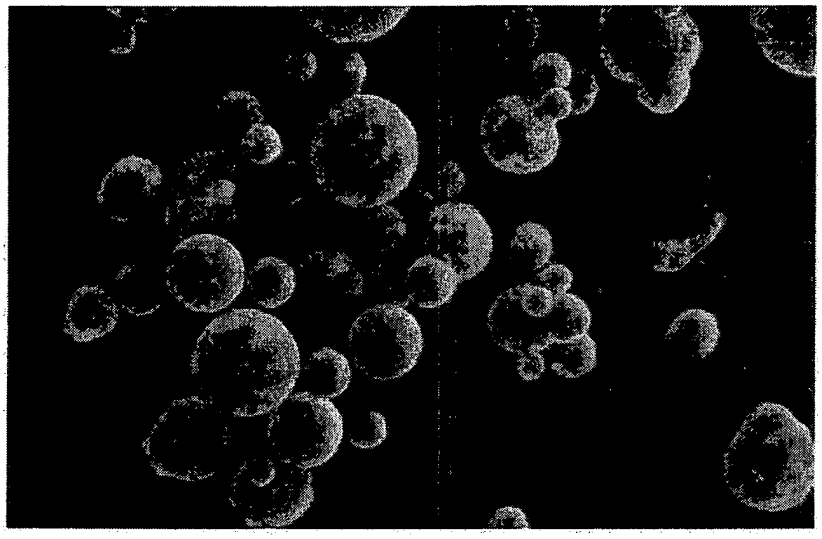
Attorney of Record
MICHAEL R. GRAHAM

Correspondent
MICHAEL R. GRAHAM
MARSHALL, GERSTEIN AND BORUN
6300 SEARS TOWER - 233 S. WACKER DR.

CHICAGO, IL 606066402

LUBRITAB®

Hydrogenated Vegetable Oil, Type 1, NF
Hydrogenated Vegetable Oil, BP
Hydrogenated Oil, JP



All Natural Tablet &
Capsule Filling Lubricant

Sustained Release Agent

Auxiliary Tablet Binder Eliminating Capping & Lamination
Matrix-forming in Sustained Release
Nutritional Value
Provides Other Functions

JRS PHARMA

LEADING THE WORLD IN EXCIPIENTS

LUBRITAB®

Hydrogenated Vegetable Oil, Type 1, NF
Hydrogenated Vegetable Oil, BP
Hydrogenated Oil, JP

Auxiliary Tablet Binder
Eliminating Capping & Lamination
Matrix-forming in CR & SR
Nutritional Value
Provides Other Functions

LUBRITAB® (Hydrogenated Vegetable Oil, Hydrogenated Oil) is hydrogenated cotton-seed oil obtained from cotton plants grown. **LUBRITAB®** serves as a lubricant in tablet and capsule formulations at concentrations of 0.5 - 4 % (w/w), and usually in combination with talc, an anti-adherent.

LUBRITAB® may also be applied to dry granulated formulations during the slugging or roller compaction process.

Auxiliary Tablet Binder Eliminating Capping & Lamination:

LUBRITAB® is a liquid film lubricant that can be applied as an auxiliary tablet binder. It melts and re-solidifies during the compaction process, enhancing the bonding capacity of the tablet matrix resulting in a more robust tablet. It is recommended that an anti-adherent be added at a level sufficient to reduce or eliminate the associated punch adherence observed when using the **LUBRITAB®** in this application.

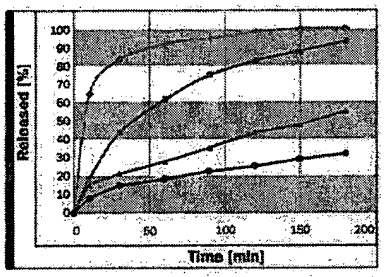
It is most effective when added in the dry state during the last blending operation before compression and blended for 10 - 15 minutes.

Characteristics:	Specifications:
Melting Range	57 - 70° C
Heavy Metals	< 0.001 %
Saponification Value	175 - 200
Loss on Drying	< 0.1%

Matrix-forming in Sustained Release:

LUBRITAB® has been employed in sustained release (SR) tablet matrix. Used in combination with soluble tableting ingredients, such as **EMDEX®** (Dextrates, NF), **LUBRITAB®** provides a cost effective SR system for API oral drug delivery.

Dissolution of Acetylsalicylic Acid



◆ without HPMC ★ HPMC 100.000 10 %
● HPMC 4.000 10% ◆ **LUBRITAB®** 10 %

The diagram shows the dissolution of acetylsalicylic acid from tablets with the following formulation :

Acetylsalicylic Acid	40,0 %
Sustained Release Agent	10,0 %
VIVAPUR® MCC 102 Microcrystalline Cellulose	49,5 %
PRUV® Sodium Stearyl Fumarate	0,5 %

Nutritional Value:

Since **LUBRITAB®** is an edible vegetable product, it is low in ash content and meets global heavy metals standards.

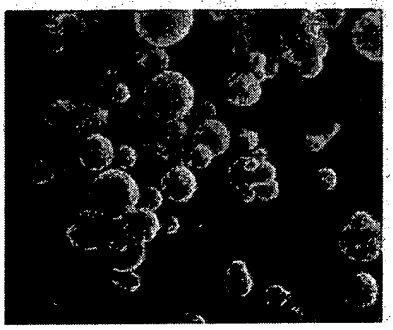
LUBRITAB® is chemically inert compared to commonly used lubricants assuring superior API quality.

LUBRITAB® is free of:
- carbohydrates
- proteins and amino acids
- starches and starch derivatives
- additives
- preservatives

Other Functions:

Other **LUBRITAB®** applications include:

- viscosity modifier in the preparation of oil-based liquid and semi-solid formulations;
- preparation of suppositories, to reduce the sedimentation of suspended components and to improve the solidification process;
- formulation of liquid and semisolid fills for hard two-piece or soft-gel capsules.



Sample Size: 100 gr, 400 gr
Packaging: 25 kg carton on 675 kg pallets

JRS PHARMA

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WORLDWIDE HEADQUARTERS
JRS PHARMA GMBH+CO.KG
Holzmühle 1
D-73494 Rosenberg (Germany)
Phone: + 49 (0) 79 67 / 1 52-0
Fax: + 49 (0) 79 67 / 1 52-345
E-mail: info@jrspharma.de
www.jrspharma.de
www.jrs.de
Customer Service: +49 (0) 7967 / 152-312

USA + CANADA
JRS PHARMA LP
2981 Route 22, Suite 1
Patterson, NY 12563-2359
Toll-Free: (800) 431-2457
Phone: +1 (845) 878-3414
Fax: +1 (845) 878-3484
E-mail: info@jrspharma.com
www.jrspharma.com
Customer Service: +1 (845) 878-3414

512468_V001_3.0070706

Apifil

Int. Cl.: 1

Prior U.S. Cl.: 51

United States Patent and Trademark Office

Reg. No. 1,278,495

Registered May 22, 1984

TRADEMARK
Principal Register

APIFIL

Etablissements Gattefosse (France corporation)
36 Chemin de Genas
Saint Priest (Rhone), France

For: BEESWAX FOR USE IN THE MANUFACTURE OF COSMETIC CREAM, in CLASS 1 (U.S. Cl. 51).

Priority claimed under Sec. 44(d) on France application No. 643,807, filed Oct. 28, 1982, Reg. No. 1,217,153, dated Oct. 28, 1982, expires Oct. 28, 1992.

Ser. No. 406,027, filed Dec. 14, 1982.

CYNTHIA B. WHITE, Examining Attorney

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This page was generated by the TARR system on 2007-12-06 15:46:03 ET

Serial Number: 73406027 Assignment Information Trademark Document Retrieval

Registration Number: 1278495

Mark (words only): APIFIL

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2004-03-26

Filing Date: 1982-12-14

Transformed into a National Application: No

Registration Date: 1984-05-22

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 900 -File Repository (Franconia)

Date In Location: 2004-03-29

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. GATTEFOSSE S.A.

Address:
GATTEFOSSE S.A.
36 CHEMIN DE GENAS
69800 SAINT-PRIEST
France
Legal Entity Type: Joint Stock Company
State or Country Where Organized: France

GOODS AND/OR SERVICES

International Class: 001
Class Status: Active
Beeswax for Use in the Manufacture of Cosmetic Cream
No Filing Basis Claimed

First Use Date: (DATE NOT AVAILABLE)
First Use in Commerce Date: (DATE NOT AVAILABLE)

ADDITIONAL INFORMATION

Foreign Application Number: 643,807
Foreign Registration Number: 1,217,153
Foreign Registration Date: 1982-10-28
Country: France
Foreign Filing Date: 1982-10-28
Foreign Expiration Date: 1992-10-28

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2004-03-26 - First renewal 10 year

2004-03-26 - Section 8 (10-year) accepted/ Section 9 granted

2004-02-13 - Combined Section 8 (10-year)/Section 9 filed

1989-10-04 - Section 8 (6-year) accepted & Section 15 acknowledged

1989-06-20 - Section 8 (6-year) and Section 15 Filed

1984-05-22 - Registered - Principal Register

1984-02-28 - Published for opposition

1984-01-18 - Notice of publication

1983-11-23 - Approved for Pub - Principal Register (Initial exam)

1983-10-27 - Communication received from applicant

1983-09-23 - Non-final action mailed

1983-08-31 - Assigned To Examiner

ATTORNEY/CORRESPONDENT INFORMATION

Attorney of Record
ARNOLD, WHITE DURKEE

Correspondent
ROGER W. PARKHURST
PARKHURST & WENDEL, LLP
1421 PRINCE ST, STE 210
ALEXANDRIA, VA 22314-2805

Domestic Representative
ARNOLD, WHITE DURKEE

APIFIL®

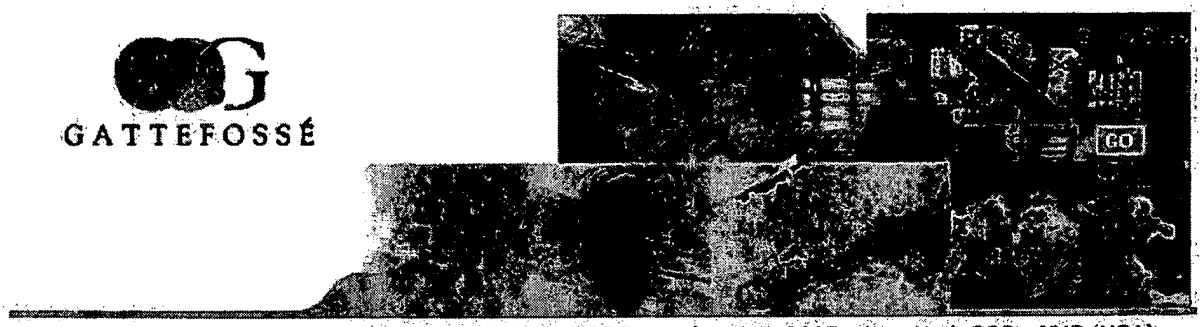
Chemical name : PEG-8 Beeswax
Physical appearance : Waxy solid-in pellets
HLB Value : 9

Applications

Apifil® is an O/W emulsifier that can be formulated with high concentrations of oily pl without phase inversion:
Used at concentrations below 5%, it forms light creams with easy spreadability (t gelifying agent is required in the aqueous phase).
Used at higher concentrations, 5% to 15%, it forms stable creams with a firm textui glossy appearance.

Topical formulations		Functions						
Creams and lotions	Micro-emulsions and gels	Emulsifying base	Thickening agent	Emollient	Penetration enhancer	Solubilizer	Surfactant	sui
✓		✓						

GATTEFOSSÉ



NEXT EVENT 12|07|07 December 6-7, 2007 - New York SCC - NYC (USA)

Gattefossé

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Products

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EMULSIFIERS FOR CREAMS AND LOTIONS

Gattefossé emulsifying bases meet the many difficulties formulators fac pharmaceutical actives such as **extremes of pH, insolubility, and heat**

These bases are consistently used to formulate dosage forms of all type fluid emulsions to anhydrous creams. With excellent **skin tolerance** emulsifying bases will help you develop safe and stable topical products.

The selection of an appropriate emulsifying base is driven by the desire consistency of the final product, the type of emulsion (O/W or W/O) specific characteristics of the active (solubility, physicochemical pro stability).

Non-Ionic O/W Emulsifiers

APIFIL®
EMULCIRE™ 61 WL 2659
GELOT™ 64
PLUROL® STEARIQUE WL 1009

Non-Ionic W/O Emulsifier

Anionic O/W Emulsifier

Akofine

Product News - Akofine

From Lipids for Care

Akofine - a series of mild natural scrubbing powders derived from pure vegetable oils.

Characteristics

Akofine powders are characterised by high oxidation stability and a good content of natural tocopherols. The high melting powdered lipid crystals are used in scrubbing formulations for mechanically gently removing dead skin cells. While refining the skin texture some part of the lipids melts by friction and helps also to smooth and relipidise the skin.

The Akofine products represents small particle sizes, the materials are free flowing and easy to handle in the production. The powder can easily be dispersed by gently mixing into a room-tempered product as the final production step before filling into the packaging.

Akofine product range

Product name	INCI name	Melting point (°C)
Akofine R	Hydrogenated Rapeseed oil	60
Akofine P	Hydrogenated Palm oil	60

Akofine powders can also be utilised to incorporate dry particles or liquid cosmetic ingredients such as flavours, extracts, pigments and vitamins, resulting in a powdered form micro-component with a shell of fat. The encapsulation can be used to protect an active ingredient and to promote a controlled delivery of cosmetic functional ingredients to the skin. Development of micro-encapsulated ingredients is performed in close collaboration with our customers.

Applications

Due to the lipophilic nature and high melting characteristics of Akofine powders they fit well into the water phase of an o/w emulsion or in a water-based gel. A nice effect is obtained when incorporating coloured Akofine particles into a transparent gel. The Akofine products are less suitable for formulations based on a high content of surfactants.

Akofine powders find applications within mild cleansing cosmetic creams and gels for face and body such as:

- Gentle cleansing, conditioning and scrubbing formulations.
- Stimulating and renewing massage and body gels.
- Firming hydrotherapy and aromatherapy products.

Karlshamns AB, Business Area Oils & Fats, Business Sector Lipids for Care, SE-374 82 Karlshamn Sweden
Phone +46 454 820 00 Fax +46 454 828 85 E-mail lipid@karlshamns.se
www.karlshamns.com

SpecialChem Cosmetics
Innovation & Solutions in

Akofine R

General Information

Trade	Akofine
Grade	Akofine R
Producer	Karlshamns
Chemical Name	
CAS Number	

Appearance	Powder, free flowing

CTFA/INCI Name	Hydrogenated Rapeseed oil

Functional Ingredient

- conditioning agents
- aesthetic enhancers (color & look) >> softening/ texturing agents

End Application

- skin care (facial care, facial cleansing, body care, baby care) >> facial care
- skin care (facial care, facial cleansing, body care, baby care) >> body care >> massage products/body oils

End Consumer Benefits

- smoothness
- vegetal origin

Comments

Hydrogenated rapeseed oil, conditioning and texturing agent. Provides high oxidation stability.

Softtisan

United States Patent Office

931,592
Registered Apr. 4, 1972

PRINCIPAL REGISTER
Trademark

Ser. No. 346,467, filed Dec. 17, 1969

SOFTISAN

Dynamit Nobel Aktiengesellschaft (German corporation)
Postfach 114–117
521 Troisdorf, Germany

For AUXILIARY AND BASIC CHEMICAL SUBSTANCES FOR PHARMACEUTICAL AND COSMETIC PREPARATIONS — NAMELY, FOUNDATIONS FOR SALVES AND CREAMS—in CLASS 6 (INT. CL. 1).

Owner of German Reg. No. 616,068, dated Apr. 20, 1951.

JOHN C. DEMOS, Examiner

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Serial Number: 72346467 Assignment Information Trademark Document Retrieval

Registration Number: 931592

Mark (words only): SOFTISAN

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2002-07-15

Filing Date: 1969-12-17

Transformed into a National Application: No

Registration Date: 1972-04-04

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 900 -File Repository (Franconia)

Date In Location: 2002-07-24

LAST APPLICANT(S)/OWNER(S) OF RECORD

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1. Sasol Germany GmbH

Address:
Sasol Germany GmbH
Anckelmannplatz 1
Hamburg D-20537
Fed Rep Germany
Legal Entity Type: Corporation
State or Country of Incorporation: Fed Rep Germany

GOODS AND/OR SERVICES

U.S. Class: 006 (International Class 001)
Class Status: Active
AUXILIARY AND BASIC CHEMICAL SUBSTANCED FOR PHARMACEUTICAL AND COSMETIC PREPARATIONS-NAMELY, FOUNDATIONS FOR SALVES AND CREAMS
No Filing Basis Claimed

First Use Date: (DATE NOT AVAILABLE)
First Use in Commerce Date: (DATE NOT AVAILABLE)

ADDITIONAL INFORMATION

Foreign Registration Number: 616068
Foreign Registration Date: 1951-04-20
Country: Fed Rep Germany

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2002-07-15 - Second renewal 10 year

2002-07-15 - Section 8 (10-year) accepted/ Section 9 granted

2002-04-04 - Combined Section 8 (10-year)/Section 9 filed

2002-04-04 - Combined Section 8 (10-year)/Section 9 filed

1992-02-12 - First renewal 10 year

1992-01-24 - Section 9 filed/check record for Section 8

1977-07-25 - Section 8 (6-year) accepted & Section 15 acknowledged

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Domestic Representative
ANTONELLI, TERY, STOUT & KRAUS, LLP

PRODUCT INFORMATION
26.13.042e/04.00

SOFTISAN® 100, 133, 134, 138, 142, 154
Hard Fats

Description
The six SOFTISAN® types, which are listed below, are specialty hard fats based on triglycerides of blends of natural, saturated, even-numbered unbranched vegetable fatty acids with a chain length of C_{10}-C_{18}. They are free of any antioxidants and stabilizers.

INCI Names
SOFTISAN® 100, 133, 134, 138, 142: Hydrogenated Coco-Glycerides
SOFTISAN® 154: Hydrogenated Palm Oil
JCIC** Name: Hydrogenated Coco Glycerides

Characteristic Values

Tests	100	133	134	138	142	154
Acid value mgKOH/g a)	max. 0.2*	max. 0.2*	max. 0.3*	max. 1.5*	max. 0.3*	max. 1*
Iodine value mg I_2/100g b)	max. 3*	max. 3*	max. 3*	max. 3*	max. 3*	max. 3*
Saponification value mgKOH/g c)	230-250*	235-255*	220-235*	215-235*	210-235*	195-210*
Hydroxyl value mgKOH/g d)	max. 15*	max. 15*	40 - 50*	max. 15*	max. 15*	max. 10*
Unsaponifiable matter % e)	max. 0.5	max. 0.5	max. 0.5	max. 3	max. 0.5	max. 1
Melting point °C f)	33.5-35.5*	32-34*	33-36*	37-40#*	42-44*	53-58*
Water % g)	max. 0.1*	max. 0.1*	max. 0.1*	max. 0.1*	max. 0.1	max. 0.1
Iodine color value mg I_2/100ml h)	max. 3	max. 3	max. 3	max. 3	max. 3*	max. 3*

= Solidification point (34-37 °C) is preferred, because of beeswax content
* = Included in Certificates of Analysis

Properties
- The above-mentioned six SOFTISAN® Hard Fat types are white masses with a neutral odor and taste.
- They are characterized by their exceptional hardness at room temperature and their sharp melting range. The narrow interval between melting and solidification points allows for rapid and economical processing. These hard fats can be heated far above their melting points, without their fast solidification time and good contractibility being altered.
- They are exceptionally resistant to oxidation, so there is no risk of rancidity.
- SOFTISAN® Hard Fats are dermatologically and toxicologically harmless.

SASOL Germany GmbH
Oleochemicals
Arthur-Imhausen-Str. 92, D-58453 Witten
Phone: +49 (0)2302/925-251 Fax: +49 (0)2302/925-358
U.S.: SASOL North America Inc., 900 Threadneedle, Houston, TX 77079
Phone: 201-666-9918 Fax: 201-666-9623

Solubility

Diethyl ether, toluene, acetone:	readily soluble
Methylene chloride:	almost insoluble
Ethanol, 96 %:	almost insoluble
Water:	almost insoluble
Fats and oils:	miscible

Applications

1. Decorative cosmetics and pharmaceutical sticks

Because of their hardness, close proximity of melting and softening, and stability against oxidation, SOFTISAN® Hard Fats are suitable as components for all types of cosmetics and pharmaceutical sticks (eyebrow pencils, lining pencils, lipsticks, grease sticks), compact and liquid makeup preparations, hot-pour products, mascaras, eye shadows, lip-gloss preparations, foundations, eyeliners etc.

These six SOFTISAN® grades offer a choice of non-smearing, non-sticky, odorless fats with different melting points and excellent skin compatibility for the preparation of the above-mentioned group of products. SOFTISAN® Hard Fats impart structure to products and have protective skin care properties. Different melting behaviors are exhibited at skin temperature, depending upon the type used.

2. Ointments and creams

Skin-spreading is improved by the addition of one of these six SOFTISAN® materials, and therefore active ingredients are readily released on the skin. Skin respiration and moisture balance are not impaired. SOFTISAN® Hard Fats "improve" the effect of paraffin hydrocarbons.

Delivery Form and Packaging

SOFTISAN® 100, 133, 134, 138, 142: pellets packed in cartons of 20 kg net.
SOFTISAN® 154: flakes packed in polyethylene-lined paper bags of 25 kg net.

Storage and Shelf Life

The products should be stored in closed containers, at cool temperatures, protected from light and moisture. Under these conditions the shelf life is at least three years.

Please refer to SASOL Material Safety Data Sheets for specific, complete information regarding the safe handling, health and environmental effects for these products.

Methods
a) EP** 2.5.1, b) DGF** G-V 11b, c) DGF C-V-3, d) DGF C-V 17a, e) EP 2.5.7, f) EP 2.2.15, g) EP 2.5.12, h) DGF G-IV 4a

** JCIC = Japanese Cosmetic Ingredient Codex
** EP = European Pharmacopoeia
** DGF = Deutsche Gesellschaft für Fettwissenschaft

Super Hartolan

ChemIndustry.com

Chemical: Super hartolan go

Enter a chemical name, CAS Number, or molecular formula.

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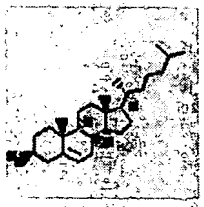
Synonyms: (-)-Cholesterol, (3H)-Cholesterol, 209124-38-9, 218965-24-3, 22243-87-0, 3-beta-Hydroxycholest-5-ene, 3.beta.-Hydroxycholest-5-ene, 3beta-Hydroxy-5-cholestene, 3beta-Hydroxycholest-5-ene, 5, 6-Cholesten-3.beta.-ol, 5-Cholesten-3.beta.-ol, 5-Cholesten-3b-ol, 57-88-5, 5:6-Cholesten-3-ol, 5:6-Cholesten-3.beta.-ol, 5:6-Cholesten-3beta-ol, 80356-14-5, AI3-03112, AIDS-080405, AIDS-338945, AIDS080405, AIDS338945, C00187, CCRIS 2834, CHEBI:16113, Cholest-5-en-3-beta-ol, Cholest-5-en-3-ol (3.beta.)-, Cholest-5-en-3-ol (3beta)-, Cholest-5-en-3-ol (3beta)-, labeled with tritium, Cholest-5-en-3-ol, (3-.beta.)-, Cholest-5-en-3-ol, (3.beta.)-, Cholest-5-en-3-ol, (3beta)-, Cholest-5-en-3.beta.-ol, Cholest-5-en-3beta-ol, Cholesterin, Cholesterine, Cholesterol, Cholesterol (JP14/NF), Cholesterol (TN), Cholesterol base H, Cholesterol [USAN:JAN], Cholesteryl alcohol, Cholestrin, Cholestrol, CLR, CMC_13392, Cordulan, D00040, delta(sup 5)-Cholesten-3-beta-ol, Delta5-Cholesten-3beta-ol, Dusoline, Dusoran, Dythol, EINECS 200-353-2, HSDB 7106, Hydrocerin, Kathro, Lanol, Lidinit, Lidinite, LMST01010001, nchembio782-comp1, Nimco cholesterol base H, Nimco cholesterol base No. 712, NSC 8798, NSC8798, Phospholipon & Cholesterol, Provitamin D, Soya phospholipon & Cholesterol (2:1 molar ratio), Super hartolan, Tegolan, Tegolan (VAN), Wool alcohols B. P., ZINC04175351



click for details

Search for: **Super hartolan**

IUPAC Name: (3S,8S,9S,10R,13R,14S,17R)-10,13-dimethyl-17-[(2R)-6-methylheptan-2-yl]-2,3,4,7,8,9,11,12,14,15,16,17-dodecahydro-1H-cyclopenta[a]phenanthren-3-ol

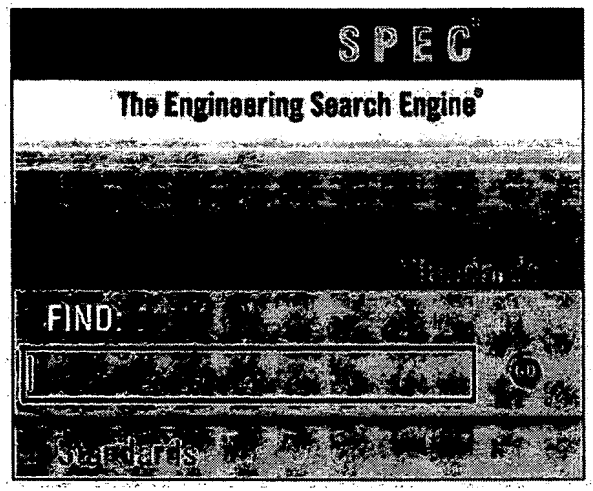
Featured Suppliers (Ads.)

CAS Number 57-88-5

Chemical Formula $C_{27}H_{46}O$

Search web sites for Super hartolan Find suppliers Find resources

previous next



Popular Chemicals

A B C D E F G H I J K L M N
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Resources

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Useful Sources archive
Free newsletters
Free magazines
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More chemical info resources

Protalan

SpecialChem Innovation & Solutions in Cosmetics

Protalan MOD

General Information

Trade	Protalan
Grade	Protalan MOD
Producer	Protameen Chemicals Inc.
Chemical Name	
CAS Number	

CTFA/INCI Name	Acetylated lanolin

Functional Ingredient

- conditioning agents
- emollients >> lanolin derivatives
- emulsifiers

End Application

- skin care (facial care, facial cleansing, body care, baby care)
- hair care (shampoos, conditioners & styling) >> conditionners & detangling products

End Consumer Benefits

- substantivity

Comments

Acetylated lanolin. Used in cleansing products, skin care and hair care. Possesses substantivity and leaves behind an elegant feel.

▸ **Quantitative Properties**

Printout from Manu.website 12/5/07

PRODUCT LISTING

Sorbitan Esters

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTACHEM SML	SORBITAN LAURATE
PROTACHEM SMO	SORBITAN OLEATE
PROTACHEM SMP	SORBITAN PALMITATE
PROTACHEM SMS - NF	SORBITAN STEARATE
PROTACHEM SOC	SORBITAN SESQUIOLEATE
PROTACHEM STO	SORBITAN TRIOLEATE
PROTACHEM STS	SORBITAN TRISTEARATE

Polyethylene Sorbitan Esters

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTASORB L-20-NF	POLYSORBATE 20
PROTASORB L-20-K [KOSHER]	POLYSORBATE 20
PROTASORB P-20	POLYSORBATE 40
PROTASORB S-20-NF	POLYSORBATE 60
PROTASORB S-20 [KOSHER]	POLYSORBATE 60
PROTASORB STS-20	POLYSORBATE 65
PROTASORB O-20-NF	POLYSORBATE 80
PROTASORB O-20-K [KOSHER]	POLYSORBATE 80
PROTASORB TO-20	POLYSORBATE 85

Polyoxyethylene & Polyoxypropylene Ethers

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROCOL LA-4	LAURETH-4
PROCOL LA-7	LAURETH-7
PROCOL LA-12	LAURETH-12
PROCOL LA-15	LAURTH-15
PROCOL LA-23	LAURETH-23
PROCOL OA-2	OLETH-2
PROCOL OA-2 SP	OLETH-2
PROCOL OA-5 SP	OLETH-5
PROCOL OA-10	OLETH-10
PROCOL OA-10 SP	OLETH-10
PROCOL OA-10 SPH	OLETH-10
PROCOL OA-20	OLETH-20
PROCOL OA-20 SP	OLETH-20
PROCOL SA-2	STEARETH-2

PROCOL SA-10	STEARETH-10
PROCOL SA-21	STEARETH-21
PROCOL SA-20	STEARETH-20
PROCOL CS-5	CETEARETH-5
PROCOL CS-15	CETEARETH-15
PROCOL CS-20	CETEARETH-20
PROCOL CS-30	CETEARETH-30
PROCOL CS-50	CETEARETH-50
PROCOL CA-2	CETETH-2
PROCOL CA-10	CETETH-10
PROCOL PSA-11	PPG-11 STEARYL ETHER
PROCOL PSA-15	PPG-11 STEARYL ETHER
PROCOL PCA-10	PPG-10 CETYL ETHER
PROCOL P	CETEARYL ALCOHOL (AND) POLYSORBATE 60 (AND) PEG 150-STEARATE (AND) STEARETH-20
PROCOL NIN	CETEARYL ALCOHOL (AND) CETETH-20
PROCOL CS-20-D	CETEARYL ALCOHOL (AND) CETEARETH 20
PROCOL ST-20-G	STEARYL ALCOHOL (AND) CETEARETH-20
PROCOL IS-20	ISOSTEARETH-20

Alkanolamides

Amine Condensate 1:2 FA-Diethanolamide

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTAMIDE X-45-B	COCAMIDE DEA
PROTAMIDE ADS-100	COCAMIDE DEA
PROTAMIDE OFO	OLEAMIDE DEA

Superamides 1:1 FA-Diethanolamides - Monoethanolamides

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTAMIDE CKD	COCAMIDE DEA
PROTAMIDE HCA-RC-3	COCAMIDE DEA
PROTAMIDE HCA-A	COCAMIDE DEA
PROTAMIDE L-80 M	LAURAMIDE DEA

PROTAMIDE L-80 MA	LAURAMIDE DEA
PROTAMIDE 1224	LAURAMIDE DEA
PROTAMIDE L-90	LAURAMIDE DEA
PROTAMIDE LMAV	LAURAMIDE DEA
PROTAMIDE LM-73	LAURAMIDE DEA (AND) MYRISTAMIDE DEA
PROTAMIDE LM-73-L	LAURAMIDE DEA (AND) MYRISTAMIDE DEA
PROTAMIDE LNO	LINOLEAMIDE DEA
PROTAMIDE 15-W	LINOLEAMIDE DEA
PROTAMIDE MRCA	MYRISTAMIDE DEA
PROTAMIDE MEAA	ACETAMIDE MEA
PROTAMIDE CME	COCAMIDE MEA
PROTAMIDE LME	LAURAMIDE MEA

Amphoterics

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTERIC JS	COCAMIDOPROPYL HYDROXYSULTAINE
PROTERIC CAB-LC	COCAMIDOPROPYL BETAINE
PROTERIC CDX-38	DISODIUM COCOAMPHODIACETATE
PROTERIC CEM-38	DISODIUM COCOAMPHODIPROPIONATE
PROTERIC CDL	DISODIUM COCOAMPHODIACETE (AND) SODIUM LAURAL SULFATE (AND) SODIUM LAURETH SULFATE
PROTERIC 1095	LAUROAMPHOGLYCINATE AND SODIUM TRIDECETH SULFATE
PROTACHEM ES-1	SODIUM LAURETH SULFATE

Polyethylene Glycol Esters

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTAMATE 200-OC	PEG-4 OLEATE
PROTAMATE 200-DPS	PEG-4 STEARATE
PROTAMATE 300-DPS	PEG-6 STEARATE
PROTAMATE 400-DPS	PEG-8 STEARATE
PROTAMATE 600-DPS	PEG-12 STEARATE
PROTAMATE 1540-DPS	PEG-40 STEARATE
PROTAMATE 2000-DPS	PEG-40 STEARATE
PROTAMATE 4400-DPS	PEG-100 STEARATE
PROTAMATE 200-ML	PEG-4 LAURATE
PROTAMATE 400-ML	PEG-8 LAURATE
PROTAMATE 600-ML	PEG-15 LAURATE
PROTAMATE 400-DO	PEG-8 DIOLEATE

PROTAMATE 200-DS	PEG-4 DISTEARATE
PROTAMATE 400-DS	PEG-8 DISTEARATE
PROTAMATE 600-DS	PEG-12 DISTEARATE
PROTAMATE 6000-DS	PEG-150 DISTEARATE
PROTAMATE 200-DL	PEG-8 DILAURATE
PROTAMATE 400-DL	PEG-8 DILAURATE

Polyoxyethylene Caster Oil Derivatives

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTACHEM CA-9	PEG-9 CASTOR OIL
PROTACHEM CA-30	PEG-30 CASTOR OIL
PROTACHEM CA-40	PEG-40 CASTOR OIL
PROTACHEM CA-60	PEG-60 CASTOR OIL
PROTACHEM CA-200	PEG-200 CASTOR OIL
PROTACHEM CAH-16	PEG-16 HYDROGENATED CASTOR OIL
PROTACHEM CAH-25	PEG-25 HYDROGENATED CASTOR OIL
PROTACHEM CAH-40	PEG-40 HYDROGENATED CASTOR OIL
PROTACHEM CAH-50	PEG-50 HYDROGENATED CASTOR OIL
PROTACHEM CAH-60	PEG-60 HYDROGENATED CASTOR OIL

Quaternary Compounds

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTAQUAT CT-29	CETRIMONIUM CHLORIDE
PROTAQUAT ASP	CETEARYL ALCOHOL AND PEG-40 HYDROGENATED CASTOR OIL AND STEARALKONIUM CHLORIDE
PROTAQUAT 868-P	DICETYLDIMONIUM CHLORIDE
PROTAQUAT 2HT-75	DISTEARYLDIMONIUM CHLORIDE

Ethoxylated Aliphatic Amines

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTOX C-2	PEG-2 COCAMINE
PROTOX C-5	PEG-5 COCAMINE
PROTOX C-15	PEG-15 COCAMINE
PROTOX O-10	PEG-10 OLEAMINE
PROTOX S-2	PEG-2 SOYAMINE
PROTOX T-2	PEG-2 HYDROGENATED TALLOWAMINE
PROTOX T-15	PEG-15 HYDROGENATED TALLOWAMINE

Alkyl Phenol Ethoxylates

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME

PROTACHEM NP-4	NONOXYNOL-4
PROTACHEM NP-9	NONOXYNOL-9
PROTACHEM OP-9	OCTOXYNOL-9
PROTACHEM OP-13	OCTOXYNOL 13

Methyl Taurate Esters

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTAPON T-33	SODIUM METHYL OLEOYL TAURATE
PROTAPON 24-A [24%ACTIVE]	SODIUM METHYL COCOYL TAURATE
PROTAPON 30-A [30%ACTIVE]	SODIUM METHYL COCOYL TAURATE
PROTAPON AC-85	SODIUM COCOYL ISETHIONATE

Fatty Esters and Glyceryl Esters

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTACHEM GMS-450	GLYCERYL STEARATE
PROTACHEM HMS	GLYCERYL STEARATE
PROTACHEM GMS-D	GLYCERYL STEARATE SE
PROTACHEM GMS-T	GLYCERYL STEARATE SE
PROTACHEM GMS-AS	GLYCERYL STEARATE AND SODIUM LAURYL SULFATE
PROTACHEM GMS-165	GLYCERYL STEARATE AND PEG 100-STEARATE
PROTACHEM G-5509	POLYGLYCERYL-9 STEARATE
PROTACHEM G-5566	POLYGLYCERYL-3 STEARATE
PROTACHEM MLD	GLYCERYL LAURATE
PROTACHEM GDL	GLYCERYL DILAURATE
PROTACHEM EGMS	GLYCOL STEARATE
PROTACHEM EGDS	GLYCOL DISTEARATE
PROTACHEM DGS	DIGLYCOL STEARATE
PROTACHEM 100	POLYGLYCERYL-4 OLEATE
PROTACHEM GC-7	PEG-7 GLYCERYL COCOATE
PROTACHEM 75	PEG 3350
PROTACHEM 400	PEG 400
PROTACHEM GC-30	PEG-30 GLYCERYL COCOATE
PROTACHEM AWS-100	PPG-5- CETETH-20
PROTACHEM PGMS	PROPYLENE GLYCOL STEARATE
PROTACHEM SAS	GLYCOL STEARATE AND STEARAMIDE AMP

Lanolin and Lanolin Products

Protameen Chemicals lanolin products are manufactured lanolin sourced from NON-BSE countries insuring safety and high quality.

PROTAMEEN TRADE NAME	INCI/CTFA CHEMICAL NAME
PROTALAN ANHYDROUS	LANOLIN
PROTALAN M-16	MINERAL OIL AND LANOLIN ALCOHOL
PROTALAN M-26 [CONCENTRATED]	MINERAL OIL AND LANOLIN ALCOHOL
PROTALAN L-75	PEG-75 LANOLIN
PROTALAN L75/50 [50% ACTIVE]	PEG-75 LANOLIN
PROTALAN 98	POLYSORBATE 80 AND CETYL ACETATE AND ACETYLATED LANOLIN ALCOHOL
PROTALAN AC	CETYL ACETATE AND ACETYLATED LANOLIN ALCOHOL
PROTALAN MOD	ACETYLATED LANOLIN
PROTALAN OIL	LANOLIN OIL
PROTALAN H	HYDROXYLATED LANOLIN
PROTANAL AWS	PPG-12-PEG-50 LANOLIN
PROTALAN WAX	LANOLIN WAX

PRESERVATIVES

METHYL PARABEN	METHYL PARABEN
PROPY PARABEN	PROPY PARABEN
BUTYL PARABEN	BUTYL PARABEN
ETHYL PARABEN	ETHYL PARABEN
POTASSIUM SORBATE	POTASSIUM SORBATE
SORBIC ACID	SORBIC ACID
PROTACIDE U-13	IMIDAZOLIDINYL UREA
PROTACIDE DMDMH	DMDMH HYDANTOIN
PROTACIDE NA3 EDTA	TRISODIUM EDTA
PROTACHEM NA2-P	DISODIUM EDTA

TRICLOSAN

Natural oils & Butters

NATURAL OILS & BUTTERS

COCOA BUTTER (DEODORIZED)	COCOA BUTTER
COCOA BUTTER (PPP)	COCOA BUTTER
COCONUT OIL	COCONUT OIL
SESAME OIL - USP	SESAME OIL
APRICOT KERNEL OIL	APRICOT KERNEL OIL
AVOCADO OIL	AVOCADO OIL
SHEA BUTTER	SHEA BUTTER

Fatty Alcohols

FATTY ALCOHOLS

CETYL ALCOHOL - NF	CETYL ALCOHOL
STEARYL ALCOHOL - NF	STEARYL ALCOHOL
PROTACHEM CS-50	CETEARLY ALCOHOL

Fatty Acids

FATTY ACIDS

STEARIC ACID - USP	STEARIC ACID
LAURIC ACID	LAURIC ACID
MYRISTIC ACID	MYRISTIC ACID
PALMITIC ACID	PALMITIC ACID

Humectants

HUMECTANTS

PROTACHEM GL-7	GLYCERETH - 7
PROTACHEM GL-26	GLYCERETH-26
GLYCERINE 96.5% USP	GLYCERINE
GLYCERINE 99.5%	GLYCERINE

PROTACHEM - PEG & SPECIALTY ESTERS

OTHER CHEMICAL SPECIALTIES

PROTAPHENONE 1,2,3 & 4	BENZOPHENONE 1,2,3, &4
VITAMIN C	ASCORBIC ACID
PROTDERM HA	ALPHA/BETA HYDROXY ACID BLENDS
DL-PANTHENOL	PANTHENOL
PROTACHEM 100 CG	HYDROLYZED COLLAGEN
VITAMIN E ACETATE - USP	TOCOPHERYL ACETATE
PROTACHEM SHAMPOO CONCENTRATE	SEE SPECIFICATIONS
PROTACHEM SDM	STEARAMIDOPROPYL DIMETHYLAMINE LACTATE
PROTAMIDE DIPA	DIISOPROPYL ADIPATE

PROTACHEM IPL

PROTAQUAT 70

ISOPROPYL LANOLATE

QUATERNIUM-70 / PROPYLENE GLYCOL

HOME

Akosoft

AarhusKarlshamn Sweden AB, Lipids for Care
Lipids in Pharmaceuticals

February, 2006

Product Name	Chemical Description Consistency at 20°C/70°F	Regulatory status	Applications
BIOAVAILABILITY ENHANCER			
Akoline MCM	Caprylic/capric glycerides Liquid/semi-solid	USP 24-NF 19 DMF	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
HARD FATS			
Akosoft 36	Hydrogenated Coco-glycerides Solid	EP 5th Edition	• Dermal preparations • Carrier systems for capsules
HYDROGENATED SPECIALITY OILS			
Akosol 405	Hydrogenated soybean oil Solid	USP 24-NF 19 DAB 1997	• Dermal preparations • Carrier systems for capsules
POWDERED FATS			
Akofine S	Hydrogenated soybean oil Powder	EP 5th Edition	• Dermal preparations • Carrier systems for capsules
MCT OILS			
Akomed R	Caprylic/capric triglycerides Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Akomed E	Caprylic/capric triglycerides Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
REFINED SPECIALITY OILS			
Lipex 101 Arachis oil	High in oleic and linoleic acid Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules

AarhusKarlshamn Sweden AB, Lipids for Care SE-374 82 Karlshamn Sweden Phone +46 454 820 00 Fax +46 454 828 85 E-mail lipid@aarhuskarlshamn.com www.aarhuskarlshamn.com

Product Name	Chemical Description Consistency at 20°C/70°F	Regulatory status	Applications
Rapeseed Oil Refined EP	High in oleic and linoleic acid Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Coconut Oil EP	High in lauric acid Solid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Corn oil	High in linoleic acid Liquid	USP 24-NF 19	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Soybean Oil Refined EP	High in linoleic and linolenic Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Sunflower Oil Refined EP	High in linoleic acid Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
EP **DAB** **USP-NF**	European Pharmacopoeia German Pharmacopoeia United States Pharmacopoeia - National Formulary		

Hard fats

Hard fats are used as excipients in soft gelatine capsules, suppositories and as bases in creams and ointments. The EurPh hard fats are normally based on lauric oils such as coconut and palm kernel oils that have low iodine values (low degree of unsaturation). In contrast USP-NF hard fats can be derived from long chain partially or completely hydrogenated oils such as soybean, cottonseed, palm or canola oils.

In both cases good crystallisation properties, high purity and high oxidative stability are essential.

Product range

- Akosoft 36 (EP) - excipient for gelatine capsules and for dermal preparations
- Akosol 405 (USP-NF) – excipient for gelatine capsules
- Akofine S (EP, USP-NF) – high melting excipient

Contacts
Product list
Hard fats
Refined speciality oils
Solubilisers & bioavailability enhar
High stability oils

AarhusKarlshamn AB (publ.)
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ASTON CHEMICALS
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Bicester Road, Aylesbury, HP19 8AL
Tel: +44 (0)1296 337700
Fax: +44 (0)1296 337701

Supplier: AarhusKarlshamn

(Link to AarhusKarlshamn information page)

Akosoft 36

Chemical Description	Hydrogenated Coco-Glycerides
Primary Application	Emollient
Other Applications	Oil and Fat
Description	Semi-solid emollient and texturising agent for dermo-cosmetics and similar skincare applications. High oxidative stability due to absence of unsaturation. Skin softening effect from Lauric Acid Triglycerides. Conforms to EurPh Hard fat mongraph.

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AAK

Oils & Fats

INTERNATIONAL MAGAZINE
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AAK Lipids for Care – Natural Vegetable Functional

News from

The Lipid Expert!

The go-natural trend not only persists but is growing stronger in the cosmetics, hair and skin-care segment. According to Euromonitor, the global natural cosmetics market is now worth $3.9 billion and by 2008 is expected to grow by 9%, as compared with just 1% for the conventional cosmetics and personal care market.

Natural origins, quality, traceability, ethical manufacture and the like, are high on the list of the demands of the consumer market. As a supplier of value-added ingredients, it is therefore of the utmost importance that we can produce safe, high-quality raw materials which consumers know they can rely on.

As the world's leading producer of shea butter, we make sure we can control the entire process, from raw material to the final product. We've stationed our own team of staff in West Africa, where the shea trees grow wild, so we can guarantee that our raw materials are of the very finest quality. In addition, in collaboration with the UN, we've recently completed a project that has helped improve the working conditions of the African women who harvest and shell the shea kernels (page 8).

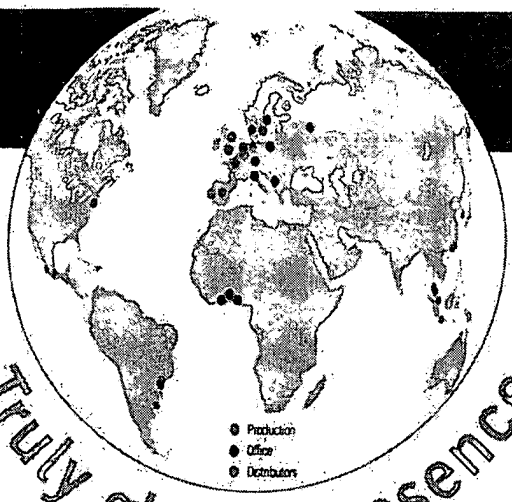
Thanks to our Lipex® Shea Family range, our Lipid Expert can easily help you formulate safe, safe cosmetic and personal care products that will deliver very high quality performance.

Health concerns and the link with food are another strong trend. Natural nutritious edible oils can also be good for the skin. Oils rich in Omega-3 and Omega-6, the so-called essential fatty acids, are of particular interest to the market right now. Scientific studies have shown that Omega-3, taken orally, has a number of health benefits – it reduces the risk of cardiovascular diseases, stimulates the circulation of the blood, prevents depression, combats inflammation of the cells and blood vessels of the brain, and softens cell membranes. Used in skin care formulations, Omega-3 is also useful for controlling skin moisturisation. Omega-6 is even more important for skin care: it contains linoleic acid, which promotes moisturisation and the barrier function of the skin. AAK's range of natural oils comprises many interesting oils with high levels of Omega-3 and Omega-6: Evening Primrose, Wheatgerm, Grapeseed and Gold-of-Pleasure oil to mention a few.

Vitamin E and Phytosterols are other compounds occurring naturally in oils that are good for the skin. Both of these are contained in Akorex L, another product available from our range (pages 4-5).

We hope that the contents of this magazine will help inspire new ideas for your product development programme. For more information, don't hesitate to get in touch with AAK's Lipid Experts, or enroll in our Oils & Fats Academy, the Lipid Experts' own training school – see page 3 or visit our website at www.aak.com.

Rita Leissner, editor



Truly global presence

The trend towards natural, vegetable-based ingredients has been gaining momentum within the cosmetics industry for several years. AAK Lipids for Care is continuously adapting to better serve existing requirements and positioning for future growth. Accordingly, AAK Lipids for Care has recently increased its investment to include direct sales, service and support for the US cosmetics and personal care industry.

Develop your products with us

AAK Lipids for Care has the broadest range of products based on Shea butter in the industry, and is second to none in its ability to offer functional, value-added vegetable oil solutions to customers in the cosmetics industry all over the world. Extensive research and development resources, along with state-of-the-art technology for the study of the chemical and physical properties of vegetable oils, form the basis for the development of new cosmetic ingredients.

"The cosmetics market is truly dynamic and relies on dedicated, qualified suppliers who can deliver the technology that will drive tomorrow's products," says Mr. John O'Keefe, head of the new Lipids for Care US group.

We serve the world

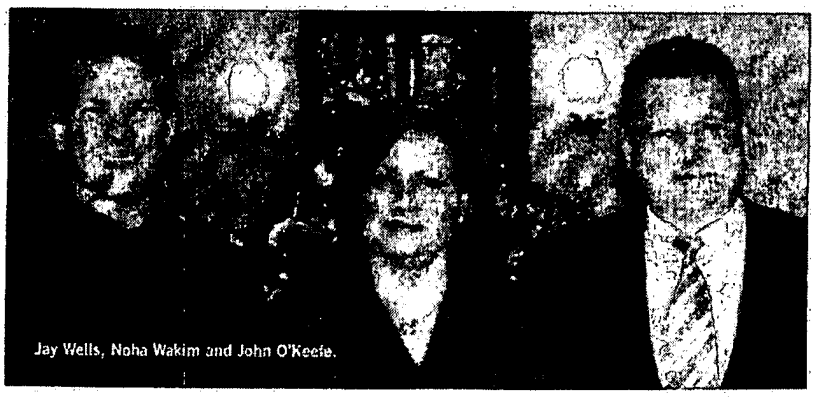
The new Lipids for Care US group is based in AAK US's existing factory at Port Newark, NJ. Alongside John O'Keefe, who has both 16 years of sales and marketing experience and a business and technical degree, Ms. Noha Wakim serves as Manager of Sales Services. Mr. Jay Wells, Technical Sales Representative, brings a degree in Chemical Biology and experience of the cosmetics industry to the group's sales function. Together, they aim to deliver the full capabilities of the global Lipids for Care Organization directly to the US market.

In addition to the US, AAK has production facilities in northern and western Europe, Mexico and Uruguay plus sales offices and a network of distributors in all the main markets of Europe, North America, Latin America and Asia. This means that AAK Lipids for Care is in an excellent position to serve customers all over the world.

Grow your business with us

AAK Lipids for Care's ambition is to introduce natural speciality lipids with new functionalities to aid customers in their product development programmes. A few examples of the current product range are presented in this magazine.

Your trusted partner AAK Lipids for Care can help you meet your customers' demands and grow your business.



Jay Wells, Noha Wakim and John O'Keefe.

AAK Oils & Fats Academy – the lipid expert training school

From left: Myriam Dormoy from Clarins, France, Aurélie Robinet, from Shiseido, France, Agnieszka Pedo, from Ziaja, Poland and Tiffany Casteret from Oriflame, Irland.

"We market ourselves as lipid experts, one way of showing this is to organise seminars for our customers," says Rita Leissner, marketing manager of Lipids for Care.

The customers are queuing up to come to Karlshamn. The second of last year's Academy seminars was held in October, attracting participants from many of Europe's leading cosmetics manufacturers. No less than ten different companies were represented. What is it, then, that makes the seminars so popular?

Besides a two-day programme jam-packed with interesting subjects, the fact that the seminar is the ideal opportunity to meet other people in the industry and exchange ideas and experience in a relaxed atmosphere is one of the reasons why so many people want to attend. One thing that all the companies share in common is a keen interest in the natural oils that AAK Lipids for Care can offer.

Don't miss the opportunity of graduating from the Oils & Fats Academy!
Coming seminars in Natural Vegetable Functional Lipids for Cosmetic Formulations this year are 29-30 May and 2-3 October.

Examples of topics:

- Lipid chemistry
- Raw materials for natural cosmetics
- Crystallisation and physical properties of lipids
- Lipid-based emulsifiers in skin care
- Control sensory aspects with vegetable lipids in skin care
- Shea Butter as a formulating tool
- Rinse-off and hair-care applications with vegetable waxes and surfactants

Application form and programme at www.aak.com

Meet AAK Lipids for Care around the world

- PCIA Asia, Guangzhou, China, 13-15 March
- In-Cosmetics, Paris, 17-19 April
- FCE, Sao Paulo, Brasil, 15-17 May
- SCC Suppliers Day, New Jersey, USA, 15-16 May
- SCC Suppliers Day, Los Angeles, 2-3 October
- Oils & Fats Academy in Karlshamn, Sweden, 29-30 May and 2-3 October
- SCS Formulate, Telford, UK, 27-28 November

Put the Shea shine in your shampoos

Lipex® Shea Surfactants
Shea butter is great in skin care but is difficult to formulate into shampoos and shower products. No longer – with the launch of the Lipex® Shea Betaine and Lipex® Shea Q, the formulator can now put shea butter into any type of shampoo, shower gel or conditioner!

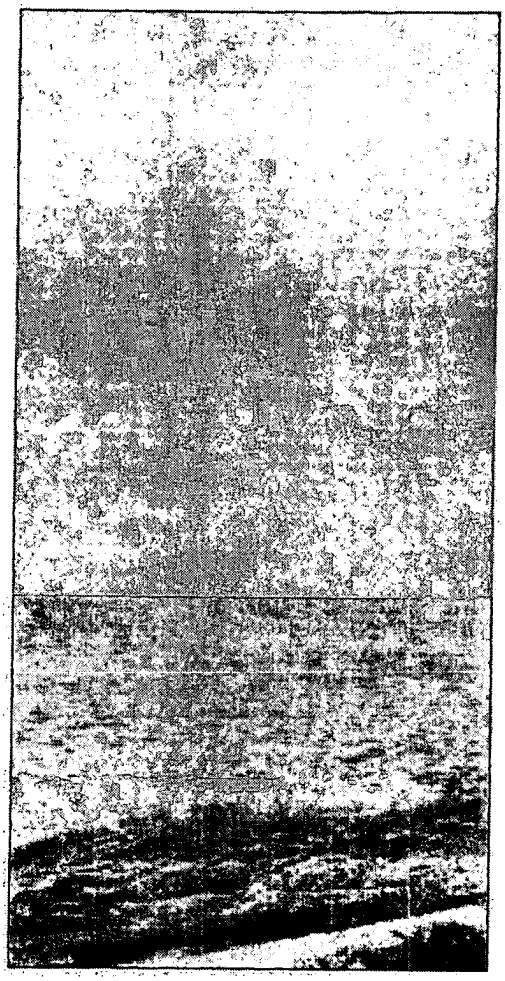
Shampoos, conditioners and shower gels
Modern shampoos and shower gels are usually formulated using a combination of an anionic surfactant, such as SLES, and an amphoteric surfactant to reduce irritancy and improve viscosity and foaming. Combine 1 part Lipex® Shea Betaine with 3-6 parts of SLES, adjust the viscosity with a pinch of salt and you have a shea butter based shampoo. Adding a small amount of a non-ionic surfactant easily makes a clear product. This combination gives mild, well-foaming shampoos that improve hair gloss and combing properties.

Equally easy is to make an accompanying conditioner with Lipex® Shea Q. Combine this cationic surfactant with your favourite cetearyl alcohol and fragrance and your new conditioner will improve hair gloss, reduce statics and make both wet and dry hair more manageable. Additional improvements can easily be made by adding a small proportion of some liquid ester or oil which is easily emulsified in the system.

Formulation guide
A formulation guide giving more detailed examples and instructions is now also available from your AAK Lipids for Care contact.

Natural lipids in skin care – from dietary fats to nutr

Natural oils are interesting ingredients for cosmetic formulations, not only as emollients but also as sources of skin nutrients such as essential fatty acids, tocopherols (Vitamin E) and phytosterols. Let us guide you into the world of natural vegetable oils that also bring functionality to your emollient blend!



Omega-6 and Omega-3: what's the difference?

There's a lot of talk nowadays about Omega-3 and Omega-6 fatty acids and their impact on the well-being of modern people. Even if this discussion is mainly about diet, an increased awareness of these fatty acids is also evident in the cosmetics industry.

Omega-3 and Omega-6 fatty acids are two groups of so called essential fatty acids – fatty acids that cannot be synthesized in our bodies, so we need to get them from our food or apply them onto our skin. The difference lies in the actual molecular structure of the fatty acids, and in each series there are a number of different fatty acids with a varying number of carbons and double bonds.

From a skin care viewpoint, Omega-6 fatty acids are the most important ones to consider. It has been known for a long time that a deficiency in linoleic acid can lead to dry skin and atopic conditions. Linoleic acid, with its two double bonds, is an important precursor of ceramides, which are important for the moisturisation and barrier function of the skin. A good source of linoleic acid is Grapeseed oil, with around 60-80% Omega-6 acids. You can also find uses for Wheatgerm oil that not only brings 50-60% Omega-6 but is also a good source for Vitamin E and phytosterols.

Another useful fatty acid in the Omega-6 series – gamma-linolenic acid – is also good at preventing dry skin, since it is a precursor of anti-inflammatory prostaglandins that can reduce the effects of inflammatory skin disorders. Gamma-linolenic acid is present in oils such as Evening Primrose (about 10%) and Borage oil (about 20%).

Omega-3 fatty acids are also metabolised to anti-inflammatory prostaglandins and are therefore important for controlling skin moisturisation and health. A proper balance between Omega-6 and Omega-3 is important and in many cultures extra supplementation of Omega-3 is necessary. Camelina oil (Gold-of-Pleasure oil) is a good source for both Omega-6 and Omega-3 in one oil: here you find 30-40% Omega-3 and around 20% Omega-6.

All polyunsaturated fatty acids are sensitive to oxidation, so you need an effective antioxidant in your formulation to protect them. Nature provides us with a very effective group of antioxidants in Vitamin E, the tocopherols.

Stability and skin healing with Vitamin E

Serious damage to skin proteins, lipids and DNA can occur if there are not enough protective antioxidants in the skin. Free radicals and reactive oxygen species will form under the influence of oxygen and UV radiation, causing inflammatory reactions and other disruptions. Free radicals are linked with decreased cell viability, contributing significantly to the skin ageing process.

Tocopherols are natural lipophilic antioxidants that stabilise biological membranes, which often contain polyunsaturated fatty acids. Alpha-tocopherol is considered to be the most effective isomer in protecting against oxidative damage and increasing skin moisturisation. The anti-inflammatory action of γ-tocopherol has been demonstrated in dietary studies. The combination of α- and γ-tocopherol found in many seed oils is interesting for the dual activity these oils can have when used as emollients in skin care.

The best sources for natural tocopherols are oils such as Wheatgerm (over 2000 ppm), Soybean (900 ppm) and Canola oil (700 ppm).

Phytosterols – membrane stabilisers and inflammation reducers

A third interesting group of lipids is the phytosterols. These compounds are important hormone and vitamin precursors but also have a physicochemical influence on the stability and barrier properties of membranes.

Phytosterols are found in vegetable oils in concentrations ranging from 0.1% to 1% with oils such as Canola and Wheatgerm oil being frequently used in cosmetics. Triterpene alcohols are unique phytosterols that can be found in high concentrations in shea butter, the fat extracted from the kernels of the shea tree (Butyrospermum parkii).

Phytosterols derived from canola oil are anti-inflammatory and have healing effects on damaged skin, especially if combined with tocophe-

icosmetics

Formulating skin care products with Natural Oils

There are a few guidelines that can help the formulator to select the most suitable vegetable oils for an application. For example, a suitable level of Omega-6 is around 1%-2% of the formulation, corresponding to about 2%-5% of natural oils. Higher levels make the formulation more sensitive to oxidation and normally bring little extra benefit in terms of skin moisturisation. The oil should be carefully processed and have a low peroxide value. For highly polyunsaturated oils, suitable antioxidants should be added directly after deodorisation. Use a combination of the polyunsaturated oils with a good emollient base comprising either fully saturated esters or monounsaturated oils such as Akorex L, a high-stability oil that not only improves stability but also brings elevated tocopherol and phytosterols levels to the formulation.

The next development: nutricosmetics?

One of today's trends is to make up nutritional deficiencies with dietary supplements, and products claiming skin health benefits are also beginning to appear on the market. A daily intake of Omega-6 and Omega-3 fatty acids assures a healthy skin, and many natural oils from AAK are used as ingredients for dietary supplements. Formulated lipid systems are also available for developing delivery systems for both lipophilic and hydrophilic actives.

Let your Lipid Experts at AAK help you into a future where the outside meets the inside for optimal skin health!

rols. It has been shown that canola oil enriched with phytosterols and tocopherols can reduce trans-epidermal water loss and erythema in damaged skin. Phytosterols also have a structural role in the skin barrier, strengthening the lipid barrier and improving dry skin conditions.

Natural sources of lipid nutrients

All these classes of skin nutrients, in different proportions, occur in vegetable oils. Table 1 lists some of the most commonly used cosmetic oils and their typical compositions. Most of these oils are usually refined and deodorised in order to make good cosmetic ingredients with low colour and odour. AAK has extensive experience of manufacturing cosmetic oils and can deliver compositions that are tailor-made for skin care, cosmetic and personal care applications.

Table 1: Composition of some common natural oils of cosmetics

	Omega-6	Omega-3	Tocopherols	Phytosterols	Comments
	%	%	ppm	ppm	
Canola oil	16-25	6-14	600	6000	
Evening primrose oil	67-86	<1	400	5000	gamma-linolenic acid 7-11%
Wheatgerm oil	50-60	≤5	2200	5600	
Grapeseed oil	60-80	≤1	600	3000	
Akorex L	<10	<1	1000	7600	

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Soft sensations

The Lipex® sensory improvers represent a group of carefully purified and designed semi-solid vegetable emollients. Soft texture and stable consistency are given by quick crystallisation and tailored melting profiles.

The selection of emollients is one of the most critical steps when formulating new skin care emulsions. The sensory properties of the formulation are strongly influenced by the physico-chemical properties of the emollients, in terms of viscosity, polarity and crystallinity. An optimised oil phase may improve ease of spreading and the sensation of lubricity and emolliency during application, and may also improve skin smoothness, perceived moisturisation and caring aspects.

When formulating with semi-solid or solid vegetable fats ("butters"), the crystallisation behaviour of the materials used must be taken into account. All Lipex® semi-solid emollients are optimised to give rapid solidification and stabilisation into the desired stable crystal form. The formation of small crystals during solidification results in improved texturising and gives good spreading properties. This makes the formulations easy to handle during production, offering stable products without risking problems with bloom formation and oil migration.

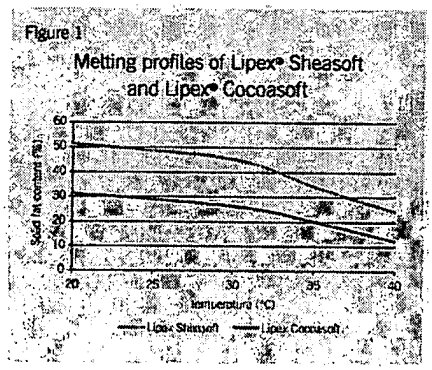
Natural soft products

A special range of semi-solid emollients with a high impact on the sensory properties of the formulation is made up of "soft" products, in which a soft room temperature texture is combined with a high melting point and significant solids contents at body temperature. These products are derived from carefully selected raw materials, such as cocoa butter, shea butter, palm oil or coconut oil, and offer a wide range of properties and cost levels for the formulator.

Non-oily skin feel

Lipex® Cocoasoft and Lipex® Sheasoft are both characterised by a relatively stable solid fat content within a broad temperature range (Figure 1). The melting profiles are tailored to offer good softening and a non-oily skin feel during and after application as well as good thermal stability. Lipex® Cocoasoft shows the most significant dry and soft after-feel. Lipex® Sheasoft utilises the combined effect of the melting profile and Shea unsaponifiables to create a film-forming lipid barrier resulting in a caring after-feel.

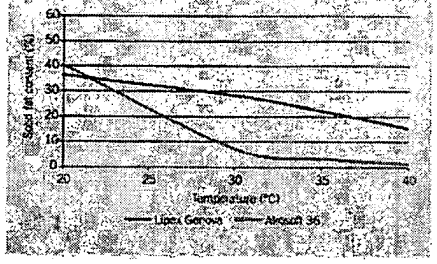
Figure 1
Melting profiles of Lipex® Sheasoft and Lipex® Cocoasoft



Cost effective alternative

Akosoft 36 and Lipex® Genova are two vegetable semisolid products characterised by a relatively high solid fats content at room temperature but melting more quickly at skin temperatures (Figure 2). This melting profile results in a typically richer skin feel owing to the higher content of the liquid phase formed on the skin surfaces during application. Akosoft 36 is a pharmacopeia-grade, fully-saturated vegetable emollient with a quick melting at skin temperatures without leaving a typically greasy after-feel. Lipex® Genova is a cost effective alternative based on palm oil for basic skin care emulsions and emulsified body butters.

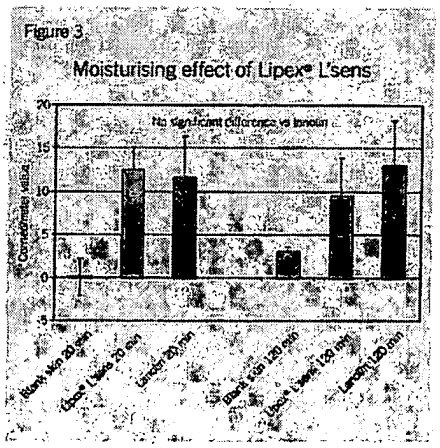
Figure 2
Melting profiles of Lipex® Genova and Akosoft 36



Long-lasting after-feel

Finally, Lipex® L'sens is characterised by a low solid fat content and a paste-like consistency at room temperature, melting quickly on the skin. To improve film-forming, its polarity is higher than the other products in the range, and it has a nice, long-lasting velvety after-feel and good moisturising capacity (Figure 3).

Figure 3
Moisturising effect of Lipex® L'sens



This selection of semi-solid emollients from the Lipex® range illustrates the many options open the formulator enabling him to choose ingredients that will have a high impact on the sensory properties of the formulation.

Cool ways to perfect body butters

Vegetable fats offer a variety of ways of controlling the sensory properties of cosmetic products, although, occasionally, one encounters difficulties that lead to stability problems and variations in consistency. However, if you're familiar with how the combined ingredients interact and how they respond to temperature changes, it's fairly straightforward to obtain a perfect product. One of the secrets lies in knowing your cooling profile.

Ingredients or processing – where to start?
In cosmetic formulations, the choice of ingredients and processing conditions are often intimately linked. To achieve the desired consistency in a lipid-based product, these two parameters must be matched.

Vegetable fats are polymorphic, i.e. they can assume different crystal forms, the most common stable forms of which are the β′ and β forms. When mixing different vegetable fats and/or waxes, it is often an advantage to ensure that the components exhibit the same stable polymorph. A system whose components are mutually compatible will show no change in appearance or consistency over time.

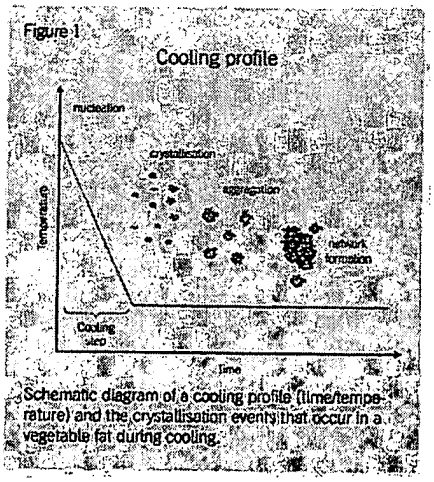
Owing to its excellent functionality, Shea butter is often used in skin care products but, has a complex crystallisation pattern and needs optimised processing conditions. Lipex® Shea, an improved shea butter, is an optimised ingredient for body butters. Thanks to its simplified crystallisation behaviour, it can be incorporated in high amounts without problems and gives the product all the benefits of shea.

Fine-tune consistency
The most important parameter for the consistency of the end product is the solid fat content, or SFC. The higher the SFC, the harder the product, and vice versa. To ensure heat stability as well, the product should contain 5-10% solids at the highest storage temperature.

To obtain a body butter with the desired solids content at different temperatures, a mixture of vegetable fats and high-melting fats or waxes can be used. To fine-tune the hardness, liquid shea emollients, such as Lipex® 205 or Lipex® Shea WL, can also be included in the formulation.

Besides adjustment of the solid fat content, the method of processing can also be used to modify the final consistency of a product. For a given solids content, the consistency is dictated by the cooling regime. Rapid cooling during processing gives firmer products, while slow cooling produces softer results. Therefore, the rate of cooling during the manufacturing process can help you ensure that your body butter will be of the desired consistency!

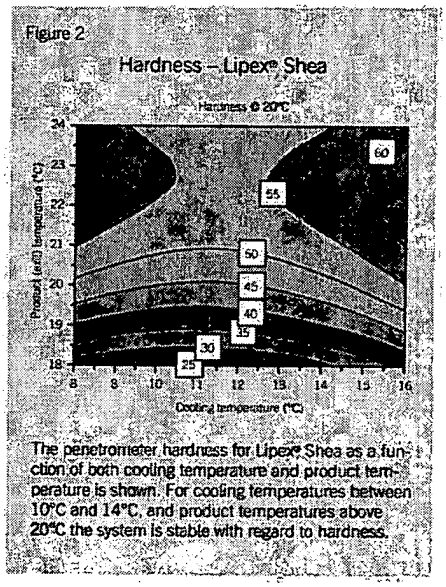
Figure 1



Schematic diagram of a cooling profile (time/temperature) and the crystallisation events that occur in a vegetable fat during cooling.

Cooling processes – not only a matter of temperature
The cooling process can easily be optimised by applying a controlled cooling profile (Figure 1) to the formulation in the container in which the product is to be packed. Three temperatures should be taken into account: the filling temperature, the temperature in the cooling cabinet or cooling tunnel, and the final temperature of the product after cooling. The filling temperature should be 5-10°C higher than the melting point of the formulation, while the cooling temperature, for most types of body butter, should be around 10-14°C. A suitable final product temperature for shea-based formulations is 20-24°C (Figure 2).

Figure 2



The penetrometer hardness for Lipex® Shea as a function of both cooling temperature and product temperature is shown. For cooling temperatures between 10°C and 14°C, and product temperatures above 20°C the system is stable with regard to hardness.

From laboratory to manufacture
From a cost-efficiency perspective, savings can be made by a fast transition from lab to production. By adopting the above recommendations, it will be easy to move on to full-scale manufacture. By controlling cooling conditions during manufacture and ensuring that the temperature of the fat blend is correct at all times, your body butter will remain stable and be of the desired consistency.

AAK team that secures the shea butter

AAK has succeeded in setting itself up as the biggest player in the West African shea trade. We now work out of five offices and sites in several different countries. Our staff, like the fruit of the shea tree, is hand-picked.

A highly interesting operation

The speciality fats produced from shea are increasingly sought after by global chocolate and cosmetics manufacturers. Our presence in the region where shea is growing enables us to control the flows of raw material in both quality and quantity. For AAK's six Scandinavians out in the field, 2007 is getting off to a flying start, since members of the AAK's board will be visiting the region to see with their own eyes what they've accomplished so far.

In control

Pär Torstensson, from Sweden was one of AAK's pioneers on the African continent. He began working in Benin, where he was commissioned to strengthen cooperation with various local players with a view to learning more about the shea trade. As a result, we now operate together with our main supplier a site comprising of offices, a warehouse, workshops and a fleet of trucks in the town of Parakou.

The operation in Africa is growing steadily, and after three years in Benin Pär has now settled in Tamale, in central Ghana, where he runs a similar site to the one in Benin together with a purchasing company we have cooperated with ever since we started to be active in Africa.

"Travel along the tiny, twisty earth roads leading to the villages is often hard going and pretty much of an adventure. But the hospitality and welcome you receive from the people once you arrive compensate for all the difficulties," says Pär Torstensson, who in this interview speaks for the six AAK Scandinavians now living in West Africa.

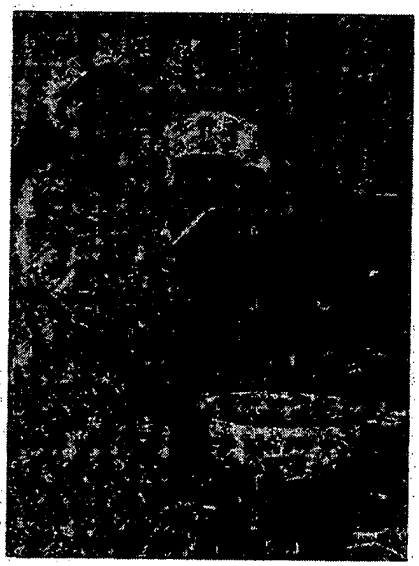
Works out in the field

Although national frontiers in Africa often cut right through tribal boundaries and have caused conflicts in many places, AAK has managed in maintaining stable bases from which we can control both the availability and quality of the valuable shea kernels.

"We have control of the supply chain and have good contacts with the local people," explains Pär Torstensson.

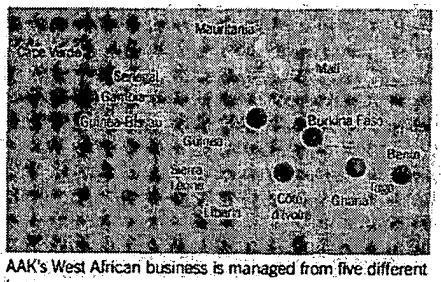
In Burkina Faso, another Scandinavian, working out of his office in the town of Bobo-Dioulasso, keeps in touch with his colleagues in Denmark and Sweden. AAK's activities in Mali are also managed from here.

AAK has since many years been sending out an expedition, starting from the Ivory Coast, to travel round the region and collect data for our "Early Warning System". By studying how and when the shea trees bloom, counting the fruit and comparing the data with previous years, we can form an impression of what the coming shea season looks like.



Shea – hard currency for African women

It's important for us to keep in touch and cooperate with the local authorities, and in particular with the women who harvest the shea kernels. Here we're participating in a UN project designed to provide village women with simple machines to drive pumps, mills, etc. These help facilitate everyday chores and, in addition, give the women more time to gather and sell shea kernels, an arrangement which provides them with an income and, in the long term, helps improve their standard of living.



AAK's West African business is managed from five different bases.

"Since poverty is still widespread in these countries and bureaucracy is part of the everyday scene, it's highly gratifying to be able to help the local population – wherever possible, we pay the money directly to them. The price naturally varies with supply and demand, but there is also a quality factor," explains Pär.

"The production methods used at the beginning of the supply chain, when the women remove the fruit and the hard outer shell, are still a far cry from the processing methods of modern industry. As a result, since we can only accept the very best raw materials, a local presence and control of the supply are of the greatest importance," says Pär, adding that many other players on the market are not nearly as particular as AAK.

The duties of our Scandinavian staff include:

- Supervising and working together with our African colleagues in order to have control of the value chain and constantly increase our network.
- Keeping in touch with our suppliers.
- Planning transport schedules enabling our trucks to collect the shea kernels at various pick-up points.
- Supervise reception, among other things by reweighing deliveries.
- Perform quality analyses of the raw material at AAK's own laboratories.
- Attend in person and ensure that everything proceeds as it should during loading for shipment to AAK's processing plants in Aarhus and Karlshamn.

International Magazine Oils & Fats published by AarhusKarlshamn Sweden AB, SE-374 82 Karlshamn, Sweden

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Production: JohnJohn AB. **Photo:** Matton, www.benfoto.se, Pär Torstensson.

AarhusKarlshamn Sweden AB www.aak.com

Akosol

AarhusKarlshamn Sweden AB, Lipids for Care
Lipids in Pharmaceuticals

February, 2006

Product Name	Chemical Description Consistency at 20°C/70°F	Regulatory status	Applications
BIOAVAILABILITY ENHANCER			
Akoline MCM	Caprylic/capric glycerides Liquid/semi-solid	USP 24-NF 19 DMF	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
HARD FATS			
Akosoft 36	Hydrogenated Coco-glycerides Solid	EP 5th Edition	• Dermal preparations • Carrier systems for capsules
HYDROGENATED SPECIALITY OILS			
Akosol 405	Hydrogenated soybean oil Solid	USP 24-NF 19 DAB 1997	• Dermal preparations • Carrier systems for capsules
POWDERED FATS			
Akofine S	Hydrogenated soybean oil Powder	EP 5th Edition	• Dermal preparations • Carrier systems for capsules
MCT OILS			
Akomed R	Caprylic/capric triglycerides Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Akomed E	Caprylic/capric triglycerides Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
REFINED SPECIALITY OILS			
Lipex 101 Arachis oil	High in oleic and linoleic acid Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules

AarhusKarlshamn Sweden AB, Lipids for Care SE-374 82 Karlshamn Sweden Phone +46 454 820 00 Fax +46 454 828 85 E-mail lipid@aarhuskarlshamn.com www.aarhuskarlshamn.com

Product Name	Chemical Description Consistency at 20°C/70°F	Regulatory status	Applications
Rapeseed Oil Refined EP	High in oleic and linoleic acid Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Coconut Oil EP	High in lauric acid Solid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Corn oil	High in linoleic acid Liquid	USP 24-NF 19	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Soybean Oil Refined EP	High in linoleic and linolenic Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
Sunflower Oil Refined EP	High in linoleic acid Liquid	EP 5th Edition	• Clinical nutrition • Dermal preparations • Carrier systems for capsules
EP **DAB** **USP-NF**	European Pharmacopoeia German Pharmacopoeia United States Pharmacopoeia - National Formulary		

HARD FATS

Hard fats are used as excipients in soft gelatine capsules, suppositories and as bases in creams and ointments. The EurPh hard fats are normally based on lauric oils such as coconut and palm kernel oils that have low iodine values (low degree of unsaturation). In contrast USP-NF hard fats can be derived from long chain partially or completely hydrogenated oils such as soybean, cottonseed, palm or canola oils.

In both cases good crystallisation properties, high purity and high oxidative stability are essential.

Product range

Akosoft 36 (EP) - excipient for gelatine capsules and for dermal preparations
Akosol 405 (USP-NF) – excipient for gelatine capsules
Akofine S (EP, USP-NF) – high melting excipient

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Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Suppository Bases, Hard Fat

1. Nonproprietary Names

BP: Hard fat
PhEur: Adeps solidus
USPNF: Hard fat

2. Synonyms

Adeps neutralis; *Akosoft*; *Akosol*; *Cremao CS-34*; *Cremao CS-36*; hydrogenated vegetable glycerides; *Massa estarinum*; *Massupol*; *Novata*; semisynthetic glycerides; *Suppocire*; *Wecobee*; *Witepsol*.

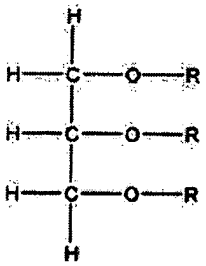
3. Chemical Name and CAS Registry Number

Hard fat triglyceride esters

4. Empirical Formula and Molecular Weight

Hard fat suppository bases consist mainly of mixtures of the triglyceride esters of the higher saturated fatty acids ($C_8H_{17}COOH$ to $C_{18}H_{37}COOH$) along with varying proportions of mono- and diglycerides. Special grades may contain additives such as beeswax, lecithin, polysorbates, ethoxylated fatty alcohols, and ethoxylated partial fatty glycerides.

5. Structural Formula



where R = H or $OC(CH_2)_nCH_3$; $n = 7–17$

Not all Rs can be H at the same time.

6. Functional Category

Suppository base.

7. Applications in Pharmaceutical Formulation or Technology

The primary application of hard fat suppository bases, or semisynthetic glycerides, is as a vehicle for the rectal or vaginal administration of a variety of drugs, either to exert local effects or to achieve systemic absorption.

Selection of a suppository base cannot usually be made in the absence of knowledge of the physicochemical properties and intrinsic thermodynamic activity of the drug substance. Other drug-related factors that can affect release and absorption and which must therefore be considered are the particle size distribution of insoluble solids, the oil : water partition coefficient, and the dissociation constant. The displacement value should also be known, as well as the ratio of drug to base. Properties of the suppository base that may or may not be modified by the drug, or that can influence drug release, are the melting characteristics, chemical reactivity, and rheology. The presence of additives in the base can also affect performance.

Melting characteristics

Fatty-based suppositories intended for systemic use should liquefy at just below body temperature. Softening or dispersion may be adequate for suppositories intended for local action or modified release. High-melting-point bases may be indicated for fat-soluble drugs that tend to depress the melting point of bases or for suppositories used in warm climates. Drugs that dissolve in bases when hot may create problems if they deposit as crystals of different form or increased size on cooling or on storage. Low-melting-point bases, particularly those that melt to liquids of low viscosity, can be of value when large volumes of insoluble substances are to be incorporated; there is a risk of sedimentation in such instances. An important factor during processing is the time required for setting. This is affected by the temperature difference between the melting point and the solidification point.[1,2]

Chemical reactivity

Although the use of bases with low hydroxyl values (low partial ester content) is indicated to minimize the risk of interaction with chemically reactive compounds, formulators should be aware that hydroxyl values are also related to hydrophilic properties, which, in turn, can modify both release and absorption rates. Bases with low hydroxyl values tend to be less plastic than those with higher values and, if cooled rapidly, may become excessively brittle. Peroxide values give a measure of the resistance of the base to oxidation and are a guide to the onset of rancidity.

Rheology

The viscosity of the melted base can affect the uniformity of distribution of suspended solids during manufacture. It can also influence the release and absorption of the drug in the rectum. Further reduction in the particle size of insoluble solids is the method of choice to minimize the risk of sedimentation. However, the presence of a high content of fine, suspended particles is likely to increase viscosity. It may also make pouring difficult, delay melting, and induce brittleness on solidification. Additives are sometimes included to modify rheological properties and to maintain homogeneity, e.g. microcrystalline wax, but the extent of their effect on drug release should first be assessed. Release from a base in which viscosity has been enhanced by an added thickener may vary and be related to the aqueous solubility of the drug itself.

Additives

Some grades of commercial bases already contain additives, and these are usually identified by the manufacturers by means of suitable letters and numbers. Additives may also be incorporated by formulators. Properties of suppositories that have been modified and additives or types of additives that have been used are shown in Table I. Water is undesirable as an additive because it enhances hydrolysis and the potential for a chemical reaction between constituents of the suppository. In low concentration, water plays little part in drug release and can serve as a medium for microbial growth.

8. Description

A white or almost white, practically odorless, waxy, brittle mass. When heated to 50°C it melts to give a colorless or slightly yellowish liquid.

9. Pharmacopeial Specifications

See Table II.

10. Typical Properties

Acid value: *see* Table III.

Color number:

≤3 for *Massa estarinum* (iodine color index);
≤3 for *Suppocire* excluding L grades (Gardener scale);
≤5 for *Suppocire* L grades (Gardener scale);
≤3 for *Witepsol* (iodine color index).

Density:

0.955–0.975 g/cm^3 for *Massa estarinum* at 20°C;
0.950–0.960 g/cm^3 for *Suppocire* at 20°C;
0.950–0.980 g/cm^3 for *Witepsol* at 20°C.

Heat of melting (22–40°C):

≈145 J/g/°C for *Massa estarinum*;
100–130 J/g/°C for *Suppocire*;
≈145 J/g/°C for *Witepsol*.

Hydroxyl value: *see* Table III.

Iodine value: *see* Table III.

Melting point: see Table III.

Moisture content:

≤0.2% w/w for *Massa estarinum*;
<0.5% w/w for *Suppocire*;
≤0.2% w/w for *Witepsol*.

Peroxide value:

≤3 for *Massa estarinum*;
≤1.2 for *Suppocire*;
≤3 for *Witepsol*.

Saponification value: *see* Table III.

Solidification point: *see* Table III.

Solubility: freely soluble in carbon tetrachloride, chloroform, ether, toluene, and xylene; slightly soluble in warm ethanol; practically insoluble in water.

Specific heat:

≈2.6 J/g/°C for *Massa estarinum*;
1.7–2.5 J/g/°C for *Suppocire*;
≈2.6 J/g/°C for *Witepsol*.

Unsaponifiable matter: *see* Table III.

11. Stability and Storage Conditions

Hard fat suppository bases are fairly stable toward oxidation and hydrolysis, with the iodine value being a measure of their resistance to oxidation and rancidity. Water content is usually low and deterioration due to hygroscopicity rarely occurs.

Melting characteristics, hardness, and drug-release profiles alter with time, and the melting point may rise by more than 1.0°C after storage for several months. Owing to the complexity of bases, elucidation of the mechanisms that induce these changes on aging is difficult. Evidence has been presented[3] that supports a finite transition from amorphous to crystalline forms in which polymorphism may or may not contribute, whereas other workers have found melting point changes to be closely associated with the conversion of triglycerides to more stable polymorphic forms.[4] Before melting point determinations are made, bases are 'conditioned' to a stable crystalline form.

Suppository bases should be stored protected from light in an airtight container at a temperature at least 5°C less than their stated melting point. Refrigeration is usually recommended for molded suppositories.

Suppositories that are not effectively packaged may develop a 'bloom' of powdery crystals at the surface. This is usually due to the presence of high-melting-point components in the base and can often be overcome by using a different base. Alternatively, the base can be precrystallized prior to pouring, since the crystals will cause a quick and complete crystallization into its end crystal form. This process is called 'tempering.'

12. Incompatibilities

Incompatibilities with suppository bases are not now extensively reported in the literature. The occurrence of a chemical reaction between a hard fat suppository base and a drug is relatively rare, but any potential for such a reaction may be indicated by the magnitude of the hydroxyl value of the base. The risk of hydrolysis of aspirin, for example, may be reduced by the use of a base with a low hydroxyl value (<5) and, additionally, by minimization of the water content of both the base and the aspirin.

There is evidence that aminophylline reacts with the glycerides in some hard fat bases to form diamides. On aging or exposure to elevated temperatures, degradation is accompanied by hardening and suppositories tend to exhibit a marked increase in melting point. The ethylenediamine content is also reduced.[5,6]

Certain fat-soluble medications, such as chloral hydrate, may depress the melting point when incorporated into a base. Similarly, when large amounts of an active substance, either solid or liquid, have to be dispersed into a base, the rheological characteristics of the resultant suppository may be changed, with concomitant effects on release and absorption. Careful selection of bases or the inclusion of additives may therefore be necessary.

13. Method of Manufacture

The most common method of manufacture involves the hydrolysis of natural vegetable oils such as coconut or palm kernel oil, followed by fractional distillation of the free fatty acids produced. The C_8 to C_{18} fractions are then hydrogenated and reesterified under controlled conditions with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value. This process is used for *Witepsol*.

In an alternative procedure, coconut or palm kernel oil is directly hydrogenated and then subjected to an interesterification either with itself or with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value, e.g. *Suppocire*.

14. Safety

Suppository bases are generally regarded as nontoxic and nonirritant materials when used in rectal formulations. However, animal studies have suggested that some bases, particularly those types with a high hydroxyl value, may be irritant to the rectal mucosa.[7]

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. There is a slight fire hazard on exposure to heat or flame.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (rectal and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17. Related Substances

Glycerin; medium-chain triglycerides; polyethylene glycol; theobroma oil.

Theobroma oil

CAS number: [8002-31-1]

Synonyms: cocoa butter; oleum cacao; oleum theobromatis.

Appearance: a yellowish or white, brittle solid with a slight odor of cocoa.

Melting point: 31–34°C

Solubility: freely soluble in chloroform, ether, and petroleum spirit; soluble in boiling ethanol; slightly soluble in ethanol (95%).

Stability and storage conditions: heating theobroma oil to more than 36°C during the preparation of suppositories can result in an appreciable lowering of the solidification point owing to the formation of metastable states; this may lead to difficulties in the setting of the suppository. Theobroma oil should be stored at a temperature not exceeding 25°C.

Comments: theobroma oil is a fat of natural origin used as a suppository base. It comprises a mixture of the triglycerides of saturated and unsaturated fatty acids, in which the unsaturated acid is preferentially situated on the 2-position of the glyceride. Theobroma oil is also a major ingredient of chocolate.

18. Comments

—

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21. Authors

RC Moreton.

22. Date of Revision

1 September 2005.

Cremao

Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Suppliers by tradename: Cremao CS-36

Sub-sections

- Aarhus United Denmark A/S (Denmark)
- Aarhus United UK Ltd (United Kingdom)
- Aarhus United USA Inc (United States)

Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Table III

Table III: Typical properties of suppository bases.

Product		Acid value	Hydroxyl value	Iodine value	Melting point (°C)	Saponification value	Solidification point (°C)	Unsaponifiable matter (%)
Cremao	CS-34	<0.3	—	<2	33–35	250	—	—
	CS-36	<0.3	—	<1	34–37	250	—	—
Massa Estarinum	B	≤0.3	20–30	≤3	33–35.5	225–240	31–33	≤0.3
	BC	≤0.3	30–40	≤3	33.5–35.5	225–240	30.5–32.5	≤0.3
	C	≤0.3	20–30	≤3	36–38	225–235	33–35	≤0.3
	299	≤0.3	≤2	≤3	33.5–35.5	240–255	32–34.5	≤0.3
Massupol	—	—	≤2	34–36	240–250	31–32.5	—	—
Massupol 15	—	—	≤3	35–37	220–230	31–33	—	—
Suppocire	A	<0.5	20–30	<2	35–36.5	225–245	—	≤0.5
	AM	<0.2	≤6	<2	35–36.5	225–245	—	≤0.5
	AML	<0.5	≤6	<2	35–36.5	225–245	—	≤0.6
	AIML	<0.5	≤6	<3	33–35	225–245	—	≤0.6
	AS_2	<0.5	15–25	<2	35–36.5	225–245	—	≤0.5
	AS_2X	<0.5	15–25	<2	35–36.5	225–245	—	≤0.6
	AT	<0.5	25–35	<2	35–36.5	225–245	—	≤0.5
	AP	<1.0	30–50	<1	33–35	200–220	—	≤0.5
	AI	<0.5	20–30	<2	33–35	225–245	—	≤0.5
	AIX	<0.5	20–30	<2	33–35	220–240	—	<0.6

AIM	<0.3	≤6	<2	33–35	225–245	—	≤0.5
AIP	<1.0	30–50	<1	30–33	205–225	—	<0.5
B	<0.5	20–30	<2	36–37.5	225–245	—	≤0.5
BM	<0.2	<6	<2	36–37.5	225–245	—	≤0.5
BML	<0.5	<6	<3	36–37.5	225–245	—	≤0.6
BS_2	<0.5	15–25	<2	36–37.5	225–245	—	≤0.5
BS_2X	<0.5	15–25	≤3	36–37.5	220–240	—	≤0.6
BT	<0.5	25–35	<2	36–37.5	225–245	—	≤0.5
BP	<1.0	30–50	<1	36–37	200–220	—	<0.5
C	<0.5	20–30	<2	38–40	220–240	—	≤0.5
CM	<0.2	<6	<2	38–40	225–245	—	≤0.5
CS_2	<0.5	15–25	<2	38–40	220–240	—	≤0.5
CS_2X	<0.5	15–25	<2	38–40	220–240	—	<0.6
CT	<0.5	25–35	<2	38–40	220–240	—	≤0.5
CP	<1.0	≤50	<1	37–39	200–220	—	<0.5
D	<0.5	20–30	<2	42–45	215–235	—	≤0.5
DM	<0.2	<6	<2	42–45	215–235	—	≤0.5
NA	<0.5	<40	<2	35.5–37.5	225–245	—	<0.5
NB	<0.5	<40	<2	36.5–38.5	215–235	—	<0.5
NC	<0.5	<40	<2	38.5–40.5	220–240	—	<0.5
NAI 0	<0.5	≤3	<2	33.5–35.5	220–245	—	<0.5
NAI 5	<0.5	≤5	<2	33.5–35.5	220–245	—	<0.5

	NAI 10	<0.5	≤15	≤2	33.5–35.5	220–245	—	≤0.5
	NAI	<0.5	<40	≤2	33.5–35.5	225–245	—	<0.5
	NAIL	<1.0	<40	≤3	33.5–35.5	225–245	—	<0.6
	NAIX	<0.5	<40	≤2	33.5–35.5	220–240	—	<0.6
	NA 0	<0.5	≤3	≤2	35.5–37.5	225–245	—	<0.5
	NA 5	<0.5	≤5	≤2	35.5–37.5	225–245	—	<0.5
	NA 10	<0.5	≤15	≤2	35.5–37.5	225–245	—	<0.5
	NAL	<0.5	<40	≤2	33.5–35.5	225–245	—	<0.6
	NAX	<0.5	<40	≤2	35.5–37.5	220–240	—	<0.6
	NBL	<0.5	<40	≤3	36.5–38.5	220–240	—	<0.6
	NBX	<0.5	<40	≤2	36.5–38.5	215–235	—	<0.6
	ND	<0.5	<40	≤2	42–45	210–230	—	<0.5
Witepsol	H5	≤0.2	≤5	≤2	34–36	235–245	33–35	≤0.3
	H12	≤0.2	5–15	≤3	32–33.5	240–255	29–33	≤0.3
	H15	≤0.2	5–15	≤3	33.5–35.5	230–245	32.5–34.5	≤0.3
	H19[a]	≤0.2	20–30	≤7	33.5–35.5	230–240	—	≤0.3
	H32	≤0.2	≤3	≤3	31–33	240–250	30–32.5	≤0.3

H35	≤0.2	≤3	≤3	33.5–35.5	240–250	32–35	≤0.3
H37	≤0.2	≤3	≤3	36–38	225–245	35–37	≤0.3
H175[a]	≤0.7	5–15	≤3	34.5–36.5	225–245	32–34.5	≤1.0
H185	≤0.2	5–15	≤3	38–39	220–235	34–37	≤0.3
W25	≤0.3	20–30	≤3	33.5–35.5	225–240	29–33	≤0.3
W31	≤0.3	25–35	≤3	35–37	225–240	30–33	≤0.5
W32	≤0.3	40–50	≤3	32–33.5	225–245	25–30	≤0.3
W35	≤0.3	40–50	≤3	33.5–35.5	225–235	27–32	≤0.3
W45	≤0.3	40–50	≤3	33.5–35.5	225–235	29–34	≤0.3
S51[a]	≤1.0	55–70	≤8	30–32	215–230	25–27	≤2.0
S52[a]	≤1.0	50–65	≤3	32–33.5	220–230	27–30	≤2.0
S55[a]	≤1.0	50–65	≤3	33.5–35.5	215–230	28–33	≤2.0
S58[a]	≤1.0	60–70	≤7	31.5–33	215–225	27–29	≤2.0
E75[a]	≤1.3	5–15	≤3	37–39	220–230	32–36	≤3.0
E76	≤0.3	30–40	≤3	37–39	220–230	31–35	≤0.5
E85	≤0.3	5–15	≤3	42–44	220–230	37–42	≤0.5

[a] Note that these types are mixtures containing hard fat and therefore do not comply with the specifications of the PhEur 2005 and USPNF 23.

Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Suppository Bases, Hard Fat

1. Nonproprietary Names

BP: Hard fat
PhEur: Adeps solidus
USPNF: Hard fat

2. Synonyms

Adeps neutralis; *Akosoft*; *Akosol*; *Cremao CS-34*; *Cremao CS-36*; hydrogenated vegetable glycerides; *Massa estarinum*; *Massupol*; *Novata*; semisynthetic glycerides; *Suppocire*; *Wecobee*; *Witepsol*.

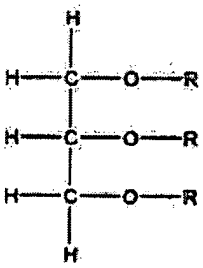
3. Chemical Name and CAS Registry Number

Hard fat triglyceride esters

4. Empirical Formula and Molecular Weight

Hard fat suppository bases consist mainly of mixtures of the triglyceride esters of the higher saturated fatty acids ($C_8H_{17}COOH$ to $C_{18}H_{37}COOH$) along with varying proportions of mono- and diglycerides. Special grades may contain additives such as beeswax, lecithin, polysorbates, ethoxylated fatty alcohols, and ethoxylated partial fatty glycerides.

5. Structural Formula



where R = H or $OC(CH_2)_nCH_3$; n = 7–17

Not all Rs can be H at the same time.

6. Functional Category

Suppository base.

7. Applications in Pharmaceutical Formulation or Technology

The primary application of hard fat suppository bases, or semisynthetic glycerides, is as a vehicle for the rectal or vaginal administration of a variety of drugs, either to exert local effects or to achieve systemic absorption.

Selection of a suppository base cannot usually be made in the absence of knowledge of the physicochemical properties and intrinsic thermodynamic activity of the drug substance. Other drug-related factors that can affect release and absorption and which must therefore be considered are the particle size distribution of insoluble solids, the oil : water partition coefficient, and the dissociation constant. The displacement value should also be known, as well as the ratio of drug to base. Properties of the suppository base that may or may not be modified by the drug, or that can influence drug release, are the melting characteristics, chemical reactivity, and rheology. The presence of additives in the base can also affect performance.

Melting characteristics

Fatty-based suppositories intended for systemic use should liquefy at just below body temperature. Softening or dispersion may be adequate for suppositories intended for local action or modified release. High-melting-point bases may be indicated for fat-soluble drugs that tend to depress the melting point of bases or for suppositories used in warm climates. Drugs that dissolve in bases when hot may create problems if they deposit as crystals of different form or increased size on cooling or on storage. Low-melting-point bases, particularly those that melt to liquids of low viscosity, can be of value when large volumes of insoluble substances are to be incorporated; there is a risk of sedimentation in such instances. An important factor during processing is the time required for setting. This is affected by the temperature difference between the melting point and the solidification point.[1,2]

Chemical reactivity

Although the use of bases with low hydroxyl values (low partial ester content) is indicated to minimize the risk of interaction with chemically reactive compounds, formulators should be aware that hydroxyl values are also related to hydrophilic properties, which, in turn, can modify both release and absorption rates. Bases with low hydroxyl values tend to be less plastic than those with higher values and, if cooled rapidly, may become excessively brittle. Peroxide values give a measure of the resistance of the base to oxidation and are a guide to the onset of rancidity.

Rheology

The viscosity of the melted base can affect the uniformity of distribution of suspended solids during manufacture. It can also influence the release and absorption of the drug in the rectum. Further reduction in the particle size of insoluble solids is the method of choice to minimize the risk of sedimentation. However, the presence of a high content of fine, suspended particles is likely to increase viscosity. It may also make pouring difficult, delay melting, and induce brittleness on solidification. Additives are sometimes included to modify rheological properties and to maintain homogeneity, e.g. microcrystalline wax, but the extent of their effect on drug release should first be assessed. Release from a base in which viscosity has been enhanced by an added thickener may vary and be related to the aqueous solubility of the drug itself.

Additives

Some grades of commercial bases already contain additives, and these are usually identified by the manufacturers by means of suitable letters and numbers. Additives may also be incorporated by formulators. Properties of suppositories that have been modified and additives or types of additives that have been used are shown in Table I. Water is undesirable as an additive because it enhances hydrolysis and the potential for a chemical reaction between constituents of the suppository. In low concentration, water plays little part in drug release and can serve as a medium for microbial growth.

8. Description

A white or almost white, practically odorless, waxy, brittle mass. When heated to 50°C it melts to give a colorless or slightly yellowish liquid.

9. Pharmacopeial Specifications

See Table II.

10. Typical Properties

Acid value: *see* Table III.

Color number:

≤3 for *Massa estarinum* (iodine color index);
≤3 for *Suppocire* excluding L grades (Gardener scale);
≤5 for *Suppocire* L grades (Gardener scale);
≤3 for *Witepsol* (iodine color index).

Density:

0.955–0.975 g/cm^3 for *Massa estarinum* at 20°C;
0.950–0.960 g/cm^3 for *Suppocire* at 20°C;
0.950–0.980 g/cm^3 for *Witepsol* at 20°C.

Heat of melting (22–40°C):

≈145 J/g/°C for *Massa estarinum*;
100–130 J/g/°C for *Suppocire*;
≈145 J/g/°C for *Witepsol*.

Hydroxyl value: *see* Table III.

Iodine value: *see* Table III.

Melting point: see Table III.

Moisture content:

≤0.2% w/w for *Massa estarinum*;
<0.5% w/w for *Suppocire*;
≤0.2% w/w for *Witepsol*.

Peroxide value:

≤3 for *Massa estarinum*;
≤1.2 for *Suppocire*;
≤3 for *Witepsol*.

Saponification value: *see* Table III.

Solidification point: *see* Table III.

Solubility: freely soluble in carbon tetrachloride, chloroform, ether, toluene, and xylene; slightly soluble in warm ethanol; practically insoluble in water.

Specific heat:

≈2.6 J/g/°C for *Massa estarinum*;
1.7–2.5 J/g/°C for *Suppocire*;
≈2.6 J/g/°C for *Witepsol*.

Unsaponifiable matter: *see* Table III.

11. Stability and Storage Conditions

Hard fat suppository bases are fairly stable toward oxidation and hydrolysis, with the iodine value being a measure of their resistance to oxidation and rancidity. Water content is usually low and deterioration due to hygroscopicity rarely occurs.

Melting characteristics, hardness, and drug-release profiles alter with time, and the melting point may rise by more than 1.0°C after storage for several months. Owing to the complexity of bases, elucidation of the mechanisms that induce these changes on aging is difficult. Evidence has been presented[3] that supports a finite transition from amorphous to crystalline forms in which polymorphism may or may not contribute, whereas other workers have found melting point changes to be closely associated with the conversion of triglycerides to more stable polymorphic forms.[4] Before melting point determinations are made, bases are 'conditioned' to a stable crystalline form.

Suppository bases should be stored protected from light in an airtight container at a temperature at least 5°C less than their stated melting point. Refrigeration is usually recommended for molded suppositories.

Suppositories that are not effectively packaged may develop a 'bloom' of powdery crystals at the surface. This is usually due to the presence of high-melting-point components in the base and can often be overcome by using a different base. Alternatively, the base can be precrystallized prior to pouring, since the crystals will cause a quick and complete crystallization into its end crystal form. This process is called 'tempering.'

12. Incompatibilities

Incompatibilities with suppository bases are not now extensively reported in the literature. The occurrence of a chemical reaction between a hard fat suppository base and a drug is relatively rare, but any potential for such a reaction may be indicated by the magnitude of the hydroxyl value of the base. The risk of hydrolysis of aspirin, for example, may be reduced by the use of a base with a low hydroxyl value (<5) and, additionally, by minimization of the water content of both the base and the aspirin.

There is evidence that aminophylline reacts with the glycerides in some hard fat bases to form diamides. On aging or exposure to elevated temperatures, degradation is accompanied by hardening and suppositories tend to exhibit a marked increase in melting point. The ethylenediamine content is also reduced.[5,6]

Certain fat-soluble medications, such as chloral hydrate, may depress the melting point when incorporated into a base. Similarly, when large amounts of an active substance, either solid or liquid, have to be dispersed into a base, the rheological characteristics of the resultant suppository may be changed, with concomitant effects on release and absorption. Careful selection of bases or the inclusion of additives may therefore be necessary.

13. Method of Manufacture

The most common method of manufacture involves the hydrolysis of natural vegetable oils such as coconut or palm kernel oil, followed by fractional distillation of the free fatty acids produced. The C_8 to C_{18} fractions are then hydrogenated and reesterified under controlled conditions with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value. This process is used for *Witepsol*.

In an alternative procedure, coconut or palm kernel oil is directly hydrogenated and then subjected to an interesterification either with itself or with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value, e.g. *Suppocire*.

14. Safety

Suppository bases are generally regarded as nontoxic and nonirritant materials when used in rectal formulations. However, animal studies have suggested that some bases, particularly those types with a high hydroxyl value, may be irritant to the rectal mucosa.[7]

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. There is a slight fire hazard on exposure to heat or flame.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (rectal and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17. Related Substances

Glycerin; medium-chain triglycerides; polyethylene glycol; theobroma oil.

Theobroma oil

CAS number: [8002-31-1]

Synonyms: cocoa butter; oleum cacao; oleum theobromatis.

Appearance: a yellowish or white, brittle solid with a slight odor of cocoa.

Melting point: 31–34°C

Solubility: freely soluble in chloroform, ether, and petroleum spirit; soluble in boiling ethanol; slightly soluble in ethanol (95%).

Stability and storage conditions: heating theobroma oil to more than 36°C during the preparation of suppositories can result in an appreciable lowering of the solidification point owing to the formation of metastable states; this may lead to difficulties in the setting of the suppository. Theobroma oil should be stored at a temperature not exceeding 25°C.

Comments: theobroma oil is a fat of natural origin used as a suppository base. It comprises a mixture of the triglycerides of saturated and unsaturated fatty acids, in which the unsaturated acid is preferentially situated on the 2-position of the glyceride. Theobroma oil is also a major ingredient of chocolate.

18. Comments

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19. Specific References

1. Setnikar I, Fantelli S. Softening and liquefaction temperature of suppositories. *J Pharm Sci* 1963; **52**: 38–43. (PubMed)
2. Krówczynski L. A simple device for testing suppositories [in Polish]. *Diss Pharm* 1959; **11**: 269–273.
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4. Liversidge GG, Grant DJW, Padfield JM. Influence of physicochemical interactions on the properties of suppositories I: interactions between the constituents of fatty suppository bases. *Int J Pharm* 1981; 7: 211–223.

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7. De Muynck C, Cuvelier C, Van Steenkiste D, *et al*. Rectal mucosa damage in rabbits after subchronical application of suppository bases. *Pharm Res* 1991; **8**: 945–950. (PubMed)

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21. Authors

RC Moreton.

22. Date of Revision

1 September 2005.

Massupol

1. Nonproprietary Names

BP: Hard fat

PhEur: Adeps solidus

USP: Hard fat

2. Synonyms

Adeps neutralis; hydrogenated vegetable glycerides; *Massa estarinum*; *Massupol*; semisynthetic glycerides; *Suppocire*; *Wecobee*; *Witepsol*.

3. Chemical Name and CAS Registry Number

Hard fat triglyceride esters

4. Empirical Formula Molecular Weight

Hard fat suppository bases consist mainly of mixtures of the triglyceride esters of the higher saturated fatty acids ($C_8H_{17}COOH$ to $C_{18}H_{37}COOH$) along with varying proportions of mono- and diglycerides. Special grades may contain additives such as beeswax, lecithin, polysorbates, ethoxylated fatty alcohols, and ethoxylated partial fatty glycerides.

5. Structural Formula

Where R = -H or $-OC(CH_2)_n-CH_3$

n = 7 to 17

Not all Rs can be -OH at the same time.

6. Functional Category

Suppository base.

7. Applications in Pharmaceutical Formulation or Technology

The primary application of hard fat suppository bases, or semisynthetic glycerides, is as a vehicle for the rectal or vaginal administration of a variety of drugs, either to exert local effects or to achieve systemic absorption.

Selection of a suppository base cannot usually be made in the absence of knowledge of the physicochemical properties and intrinsic thermodynamic activity of the drug substance. Other drug-related factors that can affect release and absorption and which must therefore be considered are the

particle size distribution of insoluble solids, the oil-water partition coefficient, and the dissociation constant. The displacement value should also be known, as well as the ratio of drug to base. Properties of the suppository base which may or may not be modified by the drug, or which can influence drug release, are the melting characteristics, chemical reactivity, and rheology. The presence of additives in the base can also affect performance.

Melting characteristics: fatty-based suppositories intended for systemic use should liquefy at just below body temperature. Softening or dispersion may be adequate for suppositories intended for local action or modified release. High melting point bases may be indicated for fat-soluble drugs which tend to depress the melting point of bases or for suppositories used in warm climates. Drugs which dissolve in bases when hot may create problems if they deposit as crystals of different form or increased size on cooling or on storage. Low melting point bases, particularly those which melt to liquids of low viscosity, can be of value when large volumes of insoluble substances are to be incorporated; there is a risk of sedimentation in such instances. An important factor during processing is the time required for setting. This is affected by the temperature difference between the melting point and the solidification point.[1,2]

Chemical reactivity: although the use of bases with low hydroxyl values (low partial ester content) is indicated to minimize the risk of interaction with chemically reactive compounds, formulators should be aware that hydroxyl values are also related to hydrophilic properties which, in turn, can modify both release and absorption rates. Bases with low hydroxyl values tend to be less plastic than those with higher values and, if cooled rapidly, may become excessively brittle. Peroxide values give a measure of the resistance of the base to oxidation and are a guide to the onset of rancidity.

Rheology: the viscosity of the melted base can affect the uniformity of distribution of suspended solids during manufacture. It can also influence the release and absorption of the drug in the rectum. Further reduction in the particle size of insoluble solids is the method of choice to minimize the risk of sedimentation. However, the presence of a high content of fine, suspended particles is likely to increase viscosity. It may also make pouring difficult, delay melting, and induce brittleness on solidification. Additives are sometimes included to modify rheological properties and to maintain homogeneity, but the extent of their effect on drug release should first be assessed. Release from a base in which viscosity has been enhanced by an added thickener may vary and be related to the aqueous solubility of the drug itself.

Additives: some grades of commercial bases already contain additives, and these are usually identified by the manufacturers by means of suitable letters and numbers. Additives may also be incorporated by formulators. Properties of suppositories which have been modified and additives or types of additives that have been used are listed below. Table I shows the physical properties of selected suppository bases.

Property	Additive
Dispersants	Surfactants
(release and/or	
absorption enhancers)	
Hygroscopicity	Colloidal silicon dioxide
(reduced)	
Hardeners	Beeswax
(or increasing melting point)	Cetyl alcohol
	Stearic acid
	Stearyl alcohol

	Aluminum monostearate
	(or di- and tri- stearate)
	Bentonite
	Magnesium stearate
	Colloidal silicon dioxide
Plasticizers	Glyceryl monostearate
(or decreasing melting point)	Myristyl alcohol
	Polysorbate 80
	Propylene glycol

Water is undesirable as an additive because it enhances hydrolysis and the potential for a chemical reaction between suppository constituents. In low concentration, water plays little part in drug release and can serve as a medium for microbial growth.

8. Description

A white or almost white-colored, practically odorless, waxy, brittle mass. When heated to 50°C it melts to give a colorless or slightly yellowish liquid.

9. Pharmacopeial Specifications

Test	PhEur	USP
Identification	+	—
Melting range	30–45°C	27–44°C
Residue on ignition	—	≤ 0.05%
Total ash	0.05%	—
Acid value	≤ 0.5	≤ 1.0
Iodine value	≤ 3	≤ 7.0
Saponification value	210–260	215–255
Hydroxyl value	≤ 50	≤ 70
Peroxide value	≤ 3	—
Unsaponifiable matter	≤ 0.6%	≤ 3.0%
Alkaline impurities	+	+
Heavy metals	≤ 10 ppm	—

10. Typical Properties

Acid value: *see* Table I.

Color number:

≤ 3 for *Massa estarinum* (iodine color index);

≤ 3 for *Suppocire* excluding L grades (Gardener scale);

≤ 5 for *Suppocire* L grades (Gardener scale);

≤ 3 for *Witepsol* (iodine color index).

Density:

0.955-0.975 g/cm^3 for *Massa estarinum* at 20°C;

0.950-0.960 g/cm^3 for *Suppocire* at 20°C;

0.950-0.980 g/cm^3 for *Witepsol* at 20°C.

Heat for melting (22-40°C):

≈ 145 J/g/°C for *Massa estarinum*;

100-130 J/g/°C for *Suppocire*;

≈ 145 J/g/°C for *Witepsol*.

Hydroxyl value: *see* Table I.

Iodine value: *see* Table I.

Melting point: *see* Table I.

Moisture content:

≤ 0.2% w/w for *Massa estarinum*;

< 0.5% w/w for *Suppocire*;

≤ 0.2% w/w for *Witepsol*.

Peroxide value:

≤ 3 for *Massa estarinum*;

≤ 1.2 for *Suppocire*;

≤ 3 for *Witepsol*.

Saponification value: *see* Table I.

Solidification point: see Table I.

Solubility: freely soluble in carbon tetrachloride, chloroform, ether, toluene, and xylene; slightly soluble in warm ethanol; practically insoluble in water.

Specific heat:

≈ 2.6 J/g/°C for *Massa estarinum*;

1.7–2.5 J/g/°C for *Suppocire*;

≈ 2.6 J/g/°C for *Witepsol*.

Unsaponifiable matter: see Table I.

11. Stability and Storage Conditions

Hard fat suppository bases are fairly stable towards oxidation and hydrolysis with the iodine value being a measure of their resistance to oxidation and rancidity. Water content is usually low and deterioration due to hygroscopicity rarely occurs.

Melting characteristics, hardness, and drug-release profiles alter with time, and the melting point may rise more than 1.0°C after storage for several months. Due to the complexity of bases, elucidation of the mechanisms which induce these changes on aging is difficult. Evidence has been presented[3] which supports a finite transition from amorphous to crystalline forms in which polymorphism may or may not contribute, whereas other workers have found melting point changes to be closely associated with the conversion of triglycerides to more stable polymorphic forms.[4] Before melting point determinations are made, bases are 'conditioned' to a stable crystalline form.

Suppository bases should be stored protected from light in an airtight container at a temperature at least 5°C less than their stated melting point. Refrigeration is usually recommended for molded suppositories.

Suppositories which are not effectively packaged may develop a 'bloom' of powdery crystals at the surface. This is usually due to the presence of high melting point components in the base and can often be overcome by using a different base. Alternatively, the base can be precrystallized prior to pouring, since the crystals will cause a quick and complete crystallization into its end crystal form. This process is called 'tempering'.

12. Incompatibilities

Incompatibilities with suppository bases are now not extensively reported in the literature. The occurrence of a chemical reaction between a hard fat suppository base and a drug is relatively rare but any potential for such a reaction may be indicated by the magnitude of the hydroxyl value of the base. The risk of hydrolysis of aspirin, for example, may be reduced by the use of a base with a low hydroxyl value (< 5) and, additionally, by minimization of the water content of both the base and the aspirin.

There is evidence that aminophylline reacts with the glycerides in some hard fat bases to form diamides. On aging or exposure to elevated temperatures, degradation is accompanied by hardening and suppositories tend to exhibit a marked increase in melting point. The ethylene diamine content is also reduced.[5,6]

Certain fat-soluble medications, such as chloral hydrate, may depress the melting point when incorporated into a base. Similarly, when large amounts of an active substance, either solid or liquid, have to be dispersed into a base, the rheological characteristics of the resultant suppository may be changed with concomitant effects on release and absorption. Careful selection of bases or the inclusion of additives may therefore be necessary.

13. Method of Manufacture

The most common method of manufacture involves the hydrolysis of natural vegetable oils such as coconut or palm kernel oil, followed by fractional distillation of the free fatty acids produced. The C_8 to C_{18} fractions are then hydrogenated and re-esterified under controlled conditions with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value. This process is used for *Witepsol*.

In an alternative procedure, coconut or palm kernel oil is directly hydrogenated and then subjected to an interesterification with either itself or glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value, e.g., *Suppocire*.

14. Safety

Suppository bases are generally regarded as nontoxic and nonirritant materials when used in rectal formulations. However, animal studies have suggested that some bases, particularly those types with a high hydroxyl value, may be irritant to the rectal mucosa.[7]

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. There is a slight fire hazard when exposed to heat or flame.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (rectal and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17. Pharmacopeias

Eur, Int, Pol, and US.

18. Related Substances

Glycerin; medium-chain triglycerides; polyethylene glycol; theobroma oil.

Theobroma oil

CAS number: [8002-31-1]

Synonyms: cocoa butter; oleum cacao; oleum theobromatis.

Appearance: a yellowish or white-colored brittle solid with a slight odor of cocoa.

Pharmacopelas: Aust, Br, Fr, Ger, It, Jpn, Neth, Pol, and US.

Melting point: 31-34°C

Solubility: freely soluble in chloroform, ether, and petroleum spirit; soluble in boiling ethanol; slightly soluble in ethanol (95%).

Stability and storage conditions: heating theobroma oil to more than 36°C during the preparation of suppositories can result in an appreciable lowering of the solidification point due to the formation of metastable states; this may lead to difficulties in the setting of the suppository. Theobroma oil should be stored at a temperature not exceeding 25°C.

Comments: theobroma oil is a fat of natural origin used as a suppository base. It is comprised of a mixture of the triglycerides of saturated and unsaturated fatty acids, in which the unsaturated acid is preferentially situated on the 2-position of the glyceride. Theobroma oil is also a major ingredient of chocolate.

19. Comments

Cocoa butter, hard fat, and polyethylene glycol are listed under suppository bases in the USP.

20. Specific References

1. Setnikar I, Fantelli S. Softening and liquefaction temperature of suppositories. *J Pharm Sci* 1963; 52: 38-43.

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6. Taylor JB, Simpkins DE. Aminophylline suppositories: *in vitro* dissolution and bioavailability in man. *Pharm J* 1981; 227: 601-603.

7. De Muynck C, Cuvelier C, Van Steenkiste D, Bonnarens L, Remon JP. Rectal mucosa damage in rabbits after subchronical application of suppository bases. *Pharm Res* 1991; 8: 945-950.

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D Chow.

23. Date of Revision

1 January 2000

Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Table III

Table III: Typical properties of suppository bases.

Product		Acid value	Hydroxyl value	Iodine value	Melting point (°C)	Saponification value	Solidification point (°C)	Unsaponifiable matter (%)
Cremao	CS-34	<0.3	—	<2	33–35	250	—	—
	CS-36	<0.3	—	<1	34–37	250	—	—
Massa Estarinum	B	≤0.3	20–30	≤3	33–35.5	225–240	31–33	≤0.3
	BC	≤0.3	30–40	≤3	33.5–35.5	225–240	30.5–32.5	≤0.3
	C	≤0.3	20–30	≤3	36–38	225–235	33–35	≤0.3
	299	≤0.3	≤2	≤3	33.5–35.5	240–255	32–34.5	≤0.3
Massupol	—	—	≤2	34–36	240–250	31–32.5	—	—
Massupol 15	—	—	≤3	35–37	220–230	31–33	—	—
Suppocire	A	<0.5	20–30	<2	35–36.5	225–245	—	≤0.5
	AM	<0.2	≤6	<2	35–36.5	225–245	—	≤0.5
	AML	<0.5	≤6	<2	35–36.5	225–245	—	≤0.6
	AIML	<0.5	≤6	<3	33–35	225–245	—	≤0.6
	AS_2	<0.5	15–25	<2	35–36.5	225–245	—	≤0.5
	AS_2X	<0.5	15–25	<2	35–36.5	225–245	—	≤0.6
	AT	<0.5	25–35	<2	35–36.5	225–245	—	≤0.5
	AP	<1.0	30–50	<1	33–35	200–220	—	≤0.5
	AI	<0.5	20–30	<2	33–35	225–245	—	≤0.5
	AIX	<0.5	20–30	<2	33–35	220–240	—	<0.6

AIM	<0.3	<6	<2	33–35	225–245	—	≤0.5
AIP	<1.0	30–50	<1	30–33	205–225	—	<0.5
B	<0.5	20–30	<2	36–37.5	225–245	—	≤0.5
BM	<0.2	<6	<2	36–37.5	225–245	—	≤0.5
BML	<0.5	<6	<3	36–37.5	225–245	—	≤0.6
BS_2	<0.5	15–25	<2	36–37.5	225–245	—	≤0.5
BS_2X	<0.5	15–25	≤3	36–37.5	220–240	—	≤0.6
BT	<0.5	25–35	<2	36–37.5	225–245	—	≤0.5
BP	<1.0	30–50	<1	36–37	200–220	—	<0.5
C	<0.5	20–30	<2	38–40	220–240	—	≤0.5
CM	<0.2	<6	<2	38–40	225–245	—	≤0.5
CS_2	<0.5	15–25	<2	38–40	220–240	—	≤0.5
CS_2X	<0.5	15–25	<2	38–40	220–240	—	<0.6
CT	<0.5	25–35	<2	38–40	220–240	—	≤0.5
CP	<1.0	≤50	<1	37–39	200–220	—	<0.5
D	<0.5	20–30	<2	42–45	215–235	—	≤0.5
DM	<0.2	<6	<2	42–45	215–235	—	≤0.5
NA	<0.5	<40	<2	35.5–37.5	225–245	—	<0.5
NB	<0.5	≤40	<2	36.5–38.5	215–235	—	<0.5
NC	<0.5	<40	<2	38.5–40.5	220–240	—	<0.5
NAI 0	<0.5	≤3	<2	33.5–35.5	220–245	—	<0.5
NAI 5	<0.5	≤5	<2	33.5–35.5	220–245	—	<0.5

	NAI 10	<0.5	<15	<2	33.5–35.5	220–245	—	<0.5
	NAI	<0.5	<40	<2	33.5–35.5	225–245	—	<0.5
	NAIL	<1.0	<40	<3	33.5–35.5	225–245	—	<0.6
	NAIX	<0.5	<40	<2	33.5–35.5	220–240	—	<0.6
	NA 0	<0.5	≤3	<2	35.5–37.5	225–245	—	<0.5
	NA 5	<0.5	≤5	<2	35.5–37.5	225–245	—	<0.5
	NA 10	<0.5	≤15	<2	35.5–37.5	225–245	—	<0.5
	NAL	<0.5	<40	<2	33.5–35.5	225–245	—	<0.6
	NAX	<0.5	<40	<2	35.5–37.5	220–240	—	<0.6
	NBL	<0.5	<40	<3	36.5–38.5	220–240	—	<0.6
	NBX	<0.5	<40	<2	36.5–38.5	215–235	—	<0.6
	ND	<0.5	<40	<2	42–45	210–230	—	<0.5
Witepsol	H5	≤0.2	≤5	≤2	34–36	235–245	33–35	≤0.3
	H12	≤0.2	5–15	≤3	32–33.5	240–255	29–33	≤0.3
	H15	≤0.2	5–15	≤3	33.5–35.5	230–245	32.5–34.5	≤0.3
	H19[a]	≤0.2	20–30	≤7	33.5–35.5	230–240	—	≤0.3
	H32	≤0.2	≤3	≤3	31–33	240–250	30–32.5	≤0.3

H35	≤0.2	≤3	≤3	33.5–35.5	240–250	32–35	≤0.3
H37	≤0.2	≤3	≤3	36–38	225–245	35–37	≤0.3
H175[a]	≤0.7	5–15	≤3	34.5–36.5	225–245	32–34.5	≤1.0
H185	≤0.2	5–15	≤3	38–39	220–235	34–37	≤0.3
W25	≤0.3	20–30	≤3	33.5–35.5	225–240	29–33	≤0.3
W31	≤0.3	25–35	≤3	35–37	225–240	30–33	≤0.5
W32	≤0.3	40–50	≤3	32–33.5	225–245	25–30	≤0.3
W35	≤0.3	40–50	≤3	33.5–35.5	225–235	27–32	≤0.3
W45	≤0.3	40–50	≤3	33.5–35.5	225–235	29–34	≤0.3
S51[a]	≤1.0	55–70	≤8	30–32	215–230	25–27	≤2.0
S52[a]	≤1.0	50–65	≤3	32–33.5	220–230	27–30	≤2.0
S55[a]	≤1.0	50–65	≤3	33.5–35.5	215–230	28–33	≤2.0
S58[a]	≤1.0	60–70	≤7	31.5–33	215–225	27–29	≤2.0
E75[a]	≤1.3	5–15	≤3	37–39	220–230	32–36	≤3.0
E76	≤0.3	30–40	≤3	37–39	220–230	31–35	≤0.5
E85	≤0.3	5–15	≤3	42–44	220–230	37–42	≤0.5

[a] Note that these types are mixtures containing hard fat and therefore do not comply with the specifications of the PhEur 2005 and USPNF 23.

Novata

480716
480716

Applicant	HENKEL KOMMANDITGESELLSCHAFT AUF AKTIEN (Henkel KGaA)
Address	Henkelstrasse 67, 4000 Dusseldorf 1, West Germany
First Use	January 1972, in commerce, May 1980
Based On:	German Registration No. 744,978 dated January 24, 1961
Goods	Chemical products for the manufacture of suppositories

NOVATA

1341822

2

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Serial Number: 73480716 Assignment Information Trademark Document Retrieval

Registration Number: 1341822

Mark (words only): NOVATA

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2005-05-16

Filing Date: 1984-05-17

Transformed into a National Application: No

Registration Date: 1985-06-18

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

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Current Location: 830 -Post Registration

Date In Location: 2005-05-16

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

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DUESSELDORF D-40589
Fed Rep Germany
Legal Entity Type: Corporation
State or Country of Incorporation: Fed Rep Germany

GOODS AND/OR SERVICES

International Class: 001
Class Status: Active
CHEMICAL COMPOSITIONS FOR USE IN THE MANUFACTURE OF SUPPOSITORIES
Basis: 1(a)
First Use Date: 1972-01-00
First Use in Commerce Date: 1980-05-00

ADDITIONAL INFORMATION

Foreign Registration Number: 744978
Foreign Registration Date: 1961-01-24
Country: Fed Rep Germany
Foreign Filing Date: 1959-10-23
Foreign Expiration Date: 1969-10-23
Foreign Renewal Date: 1979-10-23

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2006-03-30 - TEAS Change Of Correspondence Received

2005-05-16 - First renewal 10 year

2005-05-16 - Section 8 (10-year) accepted/ Section 9 granted

2005-05-16 - Assigned To Paralegal

2005-03-22 - Combined Section 8 (10-year)/Section 9 filed

2005-03-22 - TEAS Section 8 & 9 Received

2003-09-26 - TEAS Change Of Correspondence Received

1991-10-18 - Section 8 (6-year) accepted & Section 15 acknowledged

1991-06-11 - Section 8 (6-year) and Section 15 Filed

1985-06-18 - Registered - Principal Register

1985-04-09 - Published for opposition

1985-03-08 - Notice of publication

1985-02-15 - Approved for Pub - Principal Register (Initial exam)

1985-01-15 - Assigned To Examiner

1984-09-19 - Non-final action mailed

1984-09-12 - Assigned To Examiner

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Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Suppository Bases, Hard Fat

1. Nonproprietary Names

BP: Hard fat
PhEur: Adeps solidus
USPNF: Hard fat

2. Synonyms

Adeps neutralis; *Akosoft*; *Akosol*; *Cremao CS-34*; *Cremao CS-36*; hydrogenated vegetable glycerides; *Massa estarinum*; *Massupol*; *Novata*; semisynthetic glycerides; *Suppocire*; *Wecobee*; *Witepsol*.

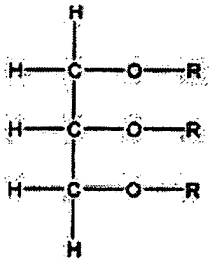
3. Chemical Name and CAS Registry Number

Hard fat triglyceride esters

4. Empirical Formula and Molecular Weight

Hard fat suppository bases consist mainly of mixtures of the triglyceride esters of the higher saturated fatty acids ($C_8H_{17}COOH$ to $C_{18}H_{37}COOH$) along with varying proportions of mono- and diglycerides. Special grades may contain additives such as beeswax, lecithin, polysorbates, ethoxylated fatty alcohols, and ethoxylated partial fatty glycerides.

5. Structural Formula



where R = H or $OC(CH_2)_nCH_3$; n = 7–17

Not all Rs can be H at the same time.

6. Functional Category

Suppository base.

7. Applications in Pharmaceutical Formulation or Technology

The primary application of hard fat suppository bases, or semisynthetic glycerides, is as a vehicle for the rectal or vaginal administration of a variety of drugs, either to exert local effects or to achieve systemic absorption.

Selection of a suppository base cannot usually be made in the absence of knowledge of the physicochemical properties and intrinsic thermodynamic activity of the drug substance. Other drug-related factors that can affect release and absorption and which must therefore be considered are the particle size distribution of insoluble solids, the oil : water partition coefficient, and the dissociation constant. The displacement value should also be known, as well as the ratio of drug to base. Properties of the suppository base that may or may not be modified by the drug, or that can influence drug release, are the melting characteristics, chemical reactivity, and rheology. The presence of additives in the base can also affect performance.

Melting characteristics

Fatty-based suppositories intended for systemic use should liquefy at just below body temperature. Softening or dispersion may be adequate for suppositories intended for local action or modified release. High-melting-point bases may be indicated for fat-soluble drugs that tend to depress the melting point of bases or for suppositories used in warm climates. Drugs that dissolve in bases when hot may create problems if they deposit as crystals of different form or increased size on cooling or on storage. Low-melting-point bases, particularly those that melt to liquids of low viscosity, can be of value when large volumes of insoluble substances are to be incorporated; there is a risk of sedimentation in such instances. An important factor during processing is the time required for setting. This is affected by the temperature difference between the melting point and the solidification point.[1,2]

Chemical reactivity

Although the use of bases with low hydroxyl values (low partial ester content) is indicated to minimize the risk of interaction with chemically reactive compounds, formulators should be aware that hydroxyl values are also related to hydrophilic properties, which, in turn, can modify both release and absorption rates. Bases with low hydroxyl values tend to be less plastic than those with higher values and, if cooled rapidly, may become excessively brittle. Peroxide values give a measure of the resistance of the base to oxidation and are a guide to the onset of rancidity.

Rheology

The viscosity of the melted base can affect the uniformity of distribution of suspended solids during manufacture. It can also influence the release and absorption of the drug in the rectum. Further reduction in the particle size of insoluble solids is the method of choice to minimize the risk of sedimentation. However, the presence of a high content of fine, suspended particles is likely to increase viscosity. It may also make pouring difficult, delay melting, and induce brittleness on solidification. Additives are sometimes included to modify rheological properties and to maintain homogeneity, e.g. microcrystalline wax, but the extent of their effect on drug release should first be assessed. Release from a base in which viscosity has been enhanced by an added thickener may vary and be related to the aqueous solubility of the drug itself.

Additives

Some grades of commercial bases already contain additives, and these are usually identified by the manufacturers by means of suitable letters and numbers. Additives may also be incorporated by formulators. Properties of suppositories that have been modified and additives or types of additives that have been used are shown in Table I. Water is undesirable as an additive because it enhances hydrolysis and the potential for a chemical reaction between constituents of the suppository. In low concentration, water plays little part in drug release and can serve as a medium for microbial growth.

8. Description

A white or almost white, practically odorless, waxy, brittle mass. When heated to 50°C it melts to give a colorless or slightly yellowish liquid.

9. Pharmacopeial Specifications

See Table II.

10. Typical Properties

Acid value: *see* Table III.

Color number:

≤3 for *Massa estarinum* (iodine color index);
≤3 for *Suppocire* excluding L grades (Gardener scale);
≤5 for *Suppocire* L grades (Gardener scale);
≤3 for *Witepsol* (iodine color index).

Density:

0.955–0.975 g/cm^3 for *Massa estarinum* at 20°C;
0.950–0.960 g/cm^3 for *Suppocire* at 20°C;
0.950–0.980 g/cm^3 for *Witepsol* at 20°C.

Heat of melting (22–40°C):

≈145 J/g/°C for *Massa estarinum*;
100–130 J/g/°C for *Suppocire*;
≈145 J/g/°C for *Witepsol*.

Hydroxyl value: *see* Table III.

Iodine value: *see* Table III.

Melting point: see Table III.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (rectal and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17. Related Substances

Glycerin; medium-chain triglycerides; polyethylene glycol; theobroma oil.

Theobroma oil

CAS number: [8002-31-1]

Synonyms: cocoa butter; oleum cacao; oleum theobromatis.

Appearance: a yellowish or white, brittle solid with a slight odor of cocoa.

Melting point: 31–34°C.

Solubility: freely soluble in chloroform, ether, and petroleum spirit; soluble in boiling ethanol; slightly soluble in ethanol (95%).

Stability and storage conditions: heating theobroma oil to more than 36°C during the preparation of suppositories can result in an appreciable lowering of the solidification point owing to the formation of metastable states; this may lead to difficulties in the setting of the suppository. Theobroma oil should be stored at a temperature not exceeding 25°C.

Comments: theobroma oil is a fat of natural origin used as a suppository base. It comprises a mixture of the triglycerides of saturated and unsaturated fatty acids, in which the unsaturated acid is preferentially situated on the 2-position of the glyceride. Theobroma oil is also a major ingredient of chocolate.

18. Comments

—

19. Specific References

1. Setnikar I, Fantelli S. Softening and liquefaction temperature of suppositories. *J Pharm Sci* 1963; **52**: 38–43. (PubMed)
2. Krówczynski L. A simple device for testing suppositories [in Polish]. *Diss Pharm* 1959; **11**: 269–273.
3. Coben LJ, Lordi NG. Physical stability of semisynthetic suppository bases. *J Pharm Sci* 1980; **69**: 955–960. (PubMed)

United States Patent Office

934,777
Registered May 30, 1972

PRINCIPAL REGISTER
Trademark

Ser. No. 361,477, filed June 2, 1970

SUPPOCIRE

Etablissements Gattefosse Societe Anonyme (French corporation)
36 Chemin de Genas,
Saint-Priest, Rhone, France

For: CHEMICAL WITH A VEGETABLE OIL BASE FOR USE IN THE MANUFACTURE OF PHARMACEUTICAL AND COSMETIC PRODUCTS, in CLASS 6 (INT. CL. 1).

Owner of French Reg. No. 800,294, dated Aug. 28, 1969.

R. M. ROSS, Examiner

Moisture content:

≤0.2% w/w for *Massa estarinum*;
<0.5% w/w for *Suppocire*;
≤0.2% w/w for *Witepsol*.

Peroxide value:

≤3 for *Massa estarinum*;
≤1.2 for *Suppocire*;
≤3 for *Witepsol*.

Saponification value: *see* Table III.

Solidification point: *see* Table III.

Solubility: freely soluble in carbon tetrachloride, chloroform, ether, toluene, and xylene; slightly soluble in warm ethanol; practically insoluble in water.

Specific heat:

≈2.6 J/g/°C for *Massa estarinum*;
1.7–2.5 J/g/°C for *Suppocire*;
≈2.6 J/g/°C for *Witepsol*.

Unsaponifiable matter: *see* Table III.

11. Stability and Storage Conditions

Hard fat suppository bases are fairly stable toward oxidation and hydrolysis, with the iodine value being a measure of their resistance to oxidation and rancidity. Water content is usually low and deterioration due to hygroscopicity rarely occurs.

Melting characteristics, hardness, and drug-release profiles alter with time, and the melting point may rise by more than 1.0°C after storage for several months. Owing to the complexity of bases, elucidation of the mechanisms that induce these changes on aging is difficult. Evidence has been presented[3] that supports a finite transition from amorphous to crystalline forms in which polymorphism may or may not contribute, whereas other workers have found melting point changes to be closely associated with the conversion of triglycerides to more stable polymorphic forms.[4] Before melting point determinations are made, bases are 'conditioned' to a stable crystalline form.

Suppository bases should be stored protected from light in an airtight container at a temperature at least 5°C less than their stated melting point. Refrigeration is usually recommended for molded suppositories.

Suppositories that are not effectively packaged may develop a 'bloom' of powdery crystals at the surface. This is usually due to the presence of high-melting-point components in the base and can often be overcome by using a different base. Alternatively, the base can be precrystallized prior to pouring, since the crystals will cause a quick and complete crystallization into its end crystal form. This process is called 'tempering.'

12. Incompatibilities

Incompatibilities with suppository bases are not now extensively reported in the literature. The occurrence of a chemical reaction between a hard fat suppository base and a drug is relatively rare, but any potential for such a reaction may be indicated by the magnitude of the hydroxyl value of the base. The risk of hydrolysis of aspirin, for example, may be reduced by the use of a base with a low hydroxyl value (<5) and, additionally, by minimization of the water content of both the base and the aspirin.

There is evidence that aminophylline reacts with the glycerides in some hard fat bases to form diamides. On aging or exposure to elevated temperatures, degradation is accompanied by hardening and suppositories tend to exhibit a marked increase in melting point. The ethylenediamine content is also reduced.[5,6]

Certain fat-soluble medications, such as chloral hydrate, may depress the melting point when incorporated into a base. Similarly, when large amounts of an active substance, either solid or liquid, have to be dispersed into a base, the rheological characteristics of the resultant suppository may be changed, with concomitant effects on release and absorption. Careful selection of bases or the inclusion of additives may therefore be necessary.

13. Method of Manufacture

The most common method of manufacture involves the hydrolysis of natural vegetable oils such as coconut or palm kernel oil, followed by fractional distillation of the free fatty acids produced. The C_8 to C_{18} fractions are then hydrogenated and reesterified under controlled conditions with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value. This process is used for *Witepsol*.

In an alternative procedure, coconut or palm kernel oil is directly hydrogenated and then subjected to an interesterification either with itself or with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value, e.g. *Suppocire*.

14. Safety

Suppository bases are generally regarded as nontoxic and nonirritant materials when used in rectal formulations. However, animal studies have suggested that some bases, particularly those types with a high hydroxyl value, may be irritant to the rectal mucosa.[7]

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. There is a slight fire hazard on exposure to heat or flame.

4. Liversidge GG, Grant DJW, Padfield JM. Influence of physicochemical interactions on the properties of suppositories I: interactions between the constituents of fatty suppository bases. *Int J Pharm* 1981; 7: 211–223.

5. Brower JF, Juenge EC, Page DP, Dow ML. Decomposition of aminophylline in suppository formulations. *J Pharm Sci* 1980; 69: 942–945. (PubMed)

6. Taylor JB, Simpkins DE. Aminophylline suppositories: *in vitro* dissolution and bioavailability in man. *Pharm J* 1981; 227: 601–603.

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20. General References

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21. Authors

RC Moreton.

22. Date of Revision

1 September 2005.

Suppocire

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Registration Number: 934777

Mark (words only): SUPPOCIRE

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2002-07-24

Filing Date: 1970-06-02

Transformed into a National Application: No

Registration Date: 1972-05-30

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

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Current Location: 900 -File Repository (Franconia)

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LAST APPLICANT(S)/OWNER(S) OF RECORD

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State or Country of Incorporation: France

GOODS AND/OR SERVICES

U.S. Class: 006 (International Class 001)
Class Status: Active
CHEMICAL WITH A VEGETABLE OIL BASE FOR USE IN THE MANUFACTURE OF PHARMACEUTICAL AND COSMETIC PRODUCTS
No Filing Basis Claimed

First Use Date: (DATE NOT AVAILABLE)
First Use in Commerce Date: (DATE NOT AVAILABLE)

ADDITIONAL INFORMATION

Foreign Registration Number: 800294
Foreign Registration Date: 1969-08-28
Country: France

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2002-07-24 - Second renewal 10 year

2002-07-24 - Section 8 (10-year) accepted/ Section 9 granted

2002-05-09 - Combined Section 8 (10-year)/Section 9 filed

2002-05-09 - PAPER RECEIVED

1993-06-01 - First renewal 10 year

1993-01-22 - Response received for Post Registration action

1992-07-02 - Post Registration action mailed - Section 9

1992-04-10 - Section 9 filed/check record for Section 8

1977-08-09 - Section 8 (6-year) accepted & Section 15 acknowledged

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Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Suppository Bases, Hard Fat

1. Nonproprietary Names

BP: Hard fat
PhEur: Adeps solidus
USPNF: Hard fat

2. Synonyms

Adeps neutralis; *Akosoft*; *Akosol*; *Cremao CS-34*; *Cremao CS-36*; hydrogenated vegetable glycerides; *Massa estarinum*; *Massupol*; *Novata*; semisynthetic glycerides; *Suppocire*; *Wecobee*; *Witepsol*.

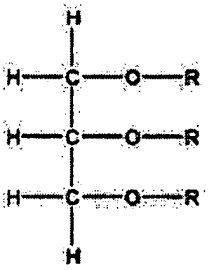
3. Chemical Name and CAS Registry Number

Hard fat triglyceride esters

4. Empirical Formula and Molecular Weight

Hard fat suppository bases consist mainly of mixtures of the triglyceride esters of the higher saturated fatty acids ($C_8H_{17}COOH$ to $C_{18}H_{37}COOH$) along with varying proportions of mono- and diglycerides. Special grades may contain additives such as beeswax, lecithin, polysorbates, ethoxylated fatty alcohols, and ethoxylated partial fatty glycerides.

5. Structural Formula



where R = H or $OC(CH_2)_nCH_3$; n = 7–17

Not all Rs can be H at the same time.

6. Functional Category

Suppository base.

7. Applications in Pharmaceutical Formulation or Technology

The primary application of hard fat suppository bases, or semisynthetic glycerides, is as a vehicle for the rectal or vaginal administration of a variety of drugs, either to exert local effects or to achieve systemic absorption.

Selection of a suppository base cannot usually be made in the absence of knowledge of the physicochemical properties and intrinsic thermodynamic activity of the drug substance. Other drug-related factors that can affect release and absorption and which must therefore be considered are the particle size distribution of insoluble solids, the oil : water partition coefficient, and the dissociation constant. The displacement value should also be known, as well as the ratio of drug to base. Properties of the suppository base that may or may not be modified by the drug, or that can influence drug release, are the melting characteristics, chemical reactivity, and rheology. The presence of additives in the base can also affect performance.

Melting characteristics

Fatty-based suppositories intended for systemic use should liquefy at just below body temperature. Softening or dispersion may be adequate for suppositories intended for local action or modified release. High-melting-point bases may be indicated for fat-soluble drugs that tend to depress the melting point of bases or for suppositories used in warm climates. Drugs that dissolve in bases when hot may create problems if they deposit as crystals of different form or increased size on cooling or on storage. Low-melting-point bases, particularly those that melt to liquids of low viscosity, can be of value when large volumes of insoluble substances are to be incorporated; there is a risk of sedimentation in such instances. An important factor during processing is the time required for setting. This is affected by the temperature difference between the melting point and the solidification point.[1,2]

Chemical reactivity

Although the use of bases with low hydroxyl values (low partial ester content) is indicated to minimize the risk of interaction with chemically reactive compounds, formulators should be aware that hydroxyl values are also related to hydrophilic properties, which, in turn, can modify both release and absorption rates. Bases with low hydroxyl values tend to be less plastic than those with higher values and, if cooled rapidly, may become excessively brittle. Peroxide values give a measure of the resistance of the base to oxidation and are a guide to the onset of rancidity.

Rheology

The viscosity of the melted base can affect the uniformity of distribution of suspended solids during manufacture. It can also influence the release and absorption of the drug in the rectum. Further reduction in the particle size of insoluble solids is the method of choice to minimize the risk of sedimentation. However, the presence of a high content of fine, suspended particles is likely to increase viscosity. It may also make pouring difficult, delay melting, and induce brittleness on solidification. Additives are sometimes included to modify rheological properties and to maintain homogeneity, e.g. microcrystalline wax, but the extent of their effect on drug release should first be assessed. Release from a base in which viscosity has been enhanced by an added thickener may vary and be related to the aqueous solubility of the drug itself.

Additives

Some grades of commercial bases already contain additives, and these are usually identified by the manufacturers by means of suitable letters and numbers. Additives may also be incorporated by formulators. Properties of suppositories that have been modified and additives or types of additives that have been used are shown in Table I. Water is undesirable as an additive because it enhances hydrolysis and the potential for a chemical reaction between constituents of the suppository. In low concentration, water plays little part in drug release and can serve as a medium for microbial growth.

8. Description

A white or almost white, practically odorless, waxy, brittle mass. When heated to 50°C it melts to give a colorless or slightly yellowish liquid.

9. Pharmacopeial Specifications

See Table II.

10. Typical Properties

Acid value: *see* Table III.

Color number:

≤3 for *Massa estarinum* (iodine color index);
≤3 for ***Suppocire*** excluding L grades (Gardener scale);
≤5 for ***Suppocire*** L grades (Gardener scale);
≤3 for *Witepsol* (iodine color index).

Density:

0.955–0.975 g/cm^3 for *Massa estarinum* at 20°C;
0.950–0.960 g/cm^3 for ***Suppocire*** at 20°C;
0.950–0.980 g/cm^3 for *Witepsol* at 20°C.

Heat of melting (22–40°C):

≈145 J/g/°C for *Massa estarinum*;
100–130 J/g/°C for ***Suppocire***;
≈145 J/g/°C for *Witepsol*.

Hydroxyl value: *see* Table III.

Iodine value: *see* Table III.

Melting point: see Table III.

Moisture content:

≤0.2% w/w for *Massa estarinum*;
<0.5% w/w for ***Suppocire***;
≤0.2% w/w for *Witepsol*.

Peroxide value:

≤3 for *Massa estarinum*;
≤1.2 for ***Suppocire***;
≤3 for *Witepsol*.

Saponification value: *see* Table III.

Solidification point: *see* Table III.

Solubility: freely soluble in carbon tetrachloride, chloroform, ether, toluene, and xylene; slightly soluble in warm ethanol; practically insoluble in water.

Specific heat:

≈2.6 J/g/°C for *Massa estarinum*;
1.7–2.5 J/g/°C for ***Suppocire***;
≈2.6 J/g/°C for *Witepsol*.

Unsaponifiable matter: *see* Table III.

11. Stability and Storage Conditions

Hard fat suppository bases are fairly stable toward oxidation and hydrolysis, with the iodine value being a measure of their resistance to oxidation and rancidity. Water content is usually low and deterioration due to hygroscopicity rarely occurs.

Melting characteristics, hardness, and drug-release profiles alter with time; and the melting point may rise by more than 1.0°C after storage for several months. Owing to the complexity of bases, elucidation of the mechanisms that induce these changes on aging is difficult. Evidence has been presented[3] that supports a finite transition from amorphous to crystalline forms in which polymorphism may or may not contribute, whereas other workers have found melting point changes to be closely associated with the conversion of triglycerides to more stable polymorphic forms.[4] Before melting point determinations are made, bases are 'conditioned' to a stable crystalline form.

Suppository bases should be stored protected from light in an airtight container at a temperature at least 5°C less than their stated melting point. Refrigeration is usually recommended for molded suppositories.

Suppositories that are not effectively packaged may develop a 'bloom' of powdery crystals at the surface. This is usually due to the presence of high-melting-point components in the base and can often be overcome by using a different base. Alternatively, the base can be precrystallized prior to pouring, since the crystals will cause a quick and complete crystallization into its end crystal form. This process is called 'tempering.'

12. Incompatibilities

Incompatibilities with suppository bases are not now extensively reported in the literature. The occurrence of a chemical reaction between a hard fat suppository base and a drug is relatively rare, but any potential for such a reaction may be indicated by the magnitude of the hydroxyl value of the base. The risk of hydrolysis of aspirin, for example, may be reduced by the use of a base with a low hydroxyl value (<5) and, additionally, by minimization of the water content of both the base and the aspirin.

There is evidence that aminophylline reacts with the glycerides in some hard fat bases to form diamides. On aging or exposure to elevated temperatures, degradation is accompanied by hardening and suppositories tend to exhibit a marked increase in melting point. The ethylenediamine content is also reduced.[5,6]

Certain fat-soluble medications, such as chloral hydrate, may depress the melting point when incorporated into a base. Similarly, when large amounts of an active substance, either solid or liquid, have to be dispersed into a base, the rheological characteristics of the resultant suppository may be changed, with concomitant effects on release and absorption. Careful selection of bases or the inclusion of additives may therefore be necessary.

13. Method of Manufacture

The most common method of manufacture involves the hydrolysis of natural vegetable oils such as coconut or palm kernel oil, followed by fractional distillation of the free fatty acids produced. The C_8 to C_{18} fractions are then hydrogenated and reesterified under controlled conditions with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value. This process is used for ***Witepsol***.

In an alternative procedure, coconut or palm kernel oil is directly hydrogenated and then subjected to an interesterification either with itself or with glycerin to form a mixture of tri-, di-, and monoglycerides of the required characteristics and hydroxyl value, e.g. ***Suppocire***.

14. Safety

Suppository bases are generally regarded as nontoxic and nonirritant materials when used in rectal formulations. However, animal studies have suggested that some bases, particularly those types with a high hydroxyl value, may be irritant to the rectal mucosa.[7]

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. There is a slight fire hazard on exposure to heat or flame.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (rectal and vaginal preparations). Included in nonparenteral medicines licensed in the UK.

17. Related Substances

Glycerin; medium-chain triglycerides; polyethylene glycol; theobroma oil.

Theobroma oil

CAS number: [8002-31-1]

Synonyms: cocoa butter; oleum cacao; oleum theobromatis.

Appearance: a yellowish or white, brittle solid with a slight odor of cocoa.

Melting point: 31–34°C

Solubility: freely soluble in chloroform, ether, and petroleum spirit; soluble in boiling ethanol; slightly soluble in ethanol (95%).

Stability and storage conditions: heating theobroma oil to more than 36°C during the preparation of suppositories can result in an appreciable lowering of the solidification point owing to the formation of metastable states; this may lead to difficulties in the setting of the suppository. Theobroma oil should be stored at a temperature not exceeding 25°C.

Comments: theobroma oil is a fat of natural origin used as a suppository base. It comprises a mixture of the triglycerides of saturated and unsaturated fatty acids, in which the unsaturated acid is preferentially situated on the 2-position of the glyceride. Theobroma oil is also a major ingredient of chocolate.

18. Comments

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21. Authors

RC Moreton.

22. Date of Revision

1 September 2005.

Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Table III

Table III: Typical properties of suppository bases.

Product		Acid value	Hydroxyl value	Iodine value	Melting point (° C)	Saponification value	Solidification point (°C)	Unsaponifiable matter (%)
Cremao	CS-34	<0.3	—	<2	33–35	250	—	—
	CS-36	<0.3	—	<1	34–37	250	—	—
Massa Estarinum	B	≤0.3	20–30	≤3	33–35.5	225–240	31–33	≤0.3
	BC	≤0.3	30–40	≤3	33.5–35.5	225–240	30.5–32.5	≤0.3
	C	≤0.3	20–30	≤3	36–38	225–235	33–35	≤0.3
	299	≤0.3	≤2	≤3	33.5–35.5	240–255	32–34.5	≤0.3
Massupol	—	—	≤2	34–36	240–250	31–32.5	—	—
Massupol 15	—	—	≤3	35–37	220–230	31–33	—	—
Suppocire	A	<0.5	20–30	<2	35–36.5	225–245	—	≤0.5
	AM	<0.2	≤6	<2	35–36.5	225–245	—	≤0.5
	AML	<0.5	≤6	<2	35–36.5	225–245	—	≤0.6
	AIML	<0.5	≤6	<3	33–35	225–245	—	≤0.6
	AS_2	<0.5	15–25	<2	35–36.5	225–245	—	≤0.5
	AS_2X	<0.5	15–25	<2	35–36.5	225–245	—	≤0.6
	AT	<0.5	25–35	<2	35–36.5	225–245	—	≤0.5
	AP	<1.0	30–50	<1	33–35	200–220	—	≤0.5
	AI	<0.5	20–30	<2	33–35	225–245	—	≤0.5
	AIX	<0.5	20–30	<2	33–35	220–240	—	<0.6

AIM	<0.3	<6	<2	33–35	225–245	—	≤0.5
AIP	<1.0	30–50	<1	30–33	205–225	—	<0.5
B	<0.5	20–30	<2	36–37.5	225–245	—	≤0.5
BM	<0.2	<6	<2	36–37.5	225–245	—	≤0.5
BML	<0.5	<6	<3	36–37.5	225–245	—	≤0.6
BS_2	<0.5	15–25	<2	36–37.5	225–245	—	≤0.5
BS_2X	<0.5	15–25	≤3	36–37.5	220–240	—	≤0.6
BT	<0.5	25–35	<2	36–37.5	225–245	—	≤0.5
BP	<1.0	30–50	<1	36–37	200–220	—	<0.5
C	<0.5	20–30	<2	38–40	220–240	—	≤0.5
CM	<0.2	<6	<2	38–40	225–245	—	≤0.5
CS_2	<0.5	15–25	<2	38–40	220–240	—	≤0.5
CS_2X	<0.5	15–25	<2	38–40	220–240	—	≤0.6
CT	<0.5	25–35	<2	38–40	220–240	—	≤0.5
CP	<1.0	≤50	<1	37–39	200–220	—	<0.5
D	<0.5	20–30	<2	42–45	215–235	—	≤0.5
DM	<0.2	<6	<2	42–45	215–235	—	≤0.5
NA	<0.5	<40	<2	35.5–37.5	225–245	—	<0.5
NB	<0.5	<40	<2	36.5–38.5	215–235	—	<0.5
NC	<0.5	<40	<2	38.5–40.5	220–240	—	<0.5
NAI 0	<0.5	≤3	<2	33.5–35.5	220–245	—	<0.5
NAI 5	<0.5	≤5	<2	33.5–35.5	220–245	—	<0.5

	NAI 10	<0.5	<15	<2	33.5–35.5	220–245	—	<0.5
	NAI	<0.5	<40	<2	33.5–35.5	225–245	—	<0.5
	NAIL	<1.0	<40	<3	33.5–35.5	225–245	—	<0.6
	NAIX	<0.5	<40	<2	33.5–35.5	220–240	—	<0.6
	NA 0	<0.5	≤3	<2	35.5–37.5	225–245	—	<0.5
	NA 5	<0.5	≤5	<2	35.5–37.5	225–245	—	<0.5
	NA 10	<0.5	≤15	<2	35.5–37.5	225–245	—	<0.5
	NAL	<0.5	<40	<2	33.5–35.5	225–245	—	<0.6
	NAX	<0.5	<40	<2	35.5–37.5	220–240	—	<0.6
	NBL	<0.5	<40	<3	36.5–38.5	220–240	—	<0.6
	NBX	<0.5	<40	<2	36.5–38.5	215–235	—	<0.6
	ND	<0.5	<40	<2	42–45	210–230	—	<0.5
Witepsol	H5	≤0.2	≤5	≤2	34–36	235–245	33–35	≤0.3
	H12	≤0.2	5–15	≤3	32–33.5	240–255	29–33	≤0.3
	H15	≤0.2	5–15	≤3	33.5–35.5	230–245	32.5–34.5	≤0.3
	H19[8]	≤0.2	20–30	≤7	33.5–35.5	230–240	—	≤0.3
	H32	≤0.2	≤3	≤3	31–33	240–250	30–32.5	≤0.3

H35	≤0.2	≤3	≤3	33.5–35.5	240–250	32–35	≤0.3
H37	≤0.2	≤3	≤3	36–38	225–245	35–37	≤0.3
H175[a]	≤0.7	5–15	≤3	34.5–36.5	225–245	32–34.5	≤1.0
H185	≤0.2	5–15	≤3	38–39	220–235	34–37	≤0.3
W25	≤0.3	20–30	≤3	33.5–35.5	225–240	29–33	≤0.3
W31	≤0.3	25–35	≤3	35–37	225–240	30–33	≤0.5
W32	≤0.3	40–50	≤3	32–33.5	225–245	25–30	≤0.3
W35	≤0.3	40–50	≤3	33.5–35.5	225–235	27–32	≤0.3
W45	≤0.3	40–50	≤3	33.5–35.5	225–235	29–34	≤0.3
S51[a]	≤1.0	55–70	≤8	30–32	215–230	25–27	≤2.0
S52[a]	≤1.0	50–65	≤3	32–33.5	220–230	27–30	≤2.0
S55[a]	≤1.0	50–65	≤3	33.5–35.5	215–230	28–33	≤2.0
S58[a]	≤1.0	60–70	≤7	31.5–33	215–225	27–29	≤2.0
E75[a]	≤1.3	5–15	≤3	37–39	220–230	32–36	≤3.0
E76	≤0.3	30–40	≤3	37–39	220–230	31–35	≤0.5
E85	≤0.3	5–15	≤3	42–44	220–230	37–42	≤0.5

[a] Note that these types are mixtures containing hard fat and therefore do not comply with the specifications of the PhEur 2005 and USPNF 23.

Wecobee

United States Patent Office

723,173
Registered Oct. 24, 1961

PRINCIPAL REGISTER
Trademark

Ser. No. 100,111, filed July 1, 1960

WECOBEE

E. F. Drew & Co., Inc. (Delaware corporation)
15 E. 26th St.
New York 10, N.Y.

For: EDIBLE VEGETABLE FAT, in CLASS 46.
First use about 1932; in commerce about 1932.

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WECOBEE

(words only): WECOBEE

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2002-02-04

Filing Date: 1960-07-01

Transformed into a National Application: No

Registration Date: 1961-10-24

Register: Principal

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22 WEST FRONTAGE ROAD
NORTHFIELD, IL 60093
United States
Legal Entity Type: Corporation
State or Country of Incorporation: Delaware

GOODS AND/OR SERVICES

U.S. Class: 046 (International Class 029)
Class Status: Active
Edible Vegetable Fat
Basis: 1(a)
First Use Date: 1932-00-00
First Use in Commerce Date: 1932-00-00

ADDITIONAL INFORMATION

(NOT AVAILABLE)

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2002-02-04 - Second renewal 10 year

2002-02-04 - Section 8 (10-year) accepted/ Section 9 granted

2001-10-19 - Combined Section 8 (10-year)/Section 9 filed

1984-10-25 - Section 8 (6-year) accepted & Section 15 acknowledged

1981-10-24 - First renewal

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Products by Tradename

Tradename: WECOBEE®

Select a Product for more details

Product Name	Chemical Description
WECOBEE® FS	HYDROGENATED VEGETABLE OIL
WECOBEE® M	HYDROGENATED VEGETABLE OIL
WECOBEE® S	HYDROGENATED VEGETABLE OIL

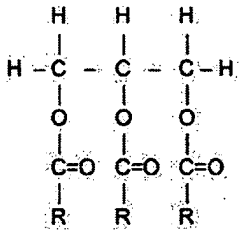
Stepan

Product Bulletin FOOD & HEALTH SPECIALTIES

Product Name

WECOBEE® FS

Chemical Structure



R = fatty acids from hydrogenated palm kernel oil

WECOBEE FS is a triglyceride derived from vegetable oil.

CAS Registry No.

68334-28-1

Applications

- Cocoa butter replacement for confectionery coatings
- Dairy toppings and baked goods
- Base for suppositories and ointments

Typical Physical Properties

Appearance	White to off-white solid
Odor and Flavor	Bland
Melting Point, °C (°F)	39.8 (103.6)
Smoke Point, °C (°F)	232.2 (450)
Flash Point, PMCC, °C (°F)	>282 (>540)
Density, g/mL (lbs/U.S. gal)	0.90 (7.5)

Solid Fat Content at 10°C	95.4
Solid Fat Content at 21.1°C	82.7
Solid Fat Content at 26.8°C	49.6
Solid Fat Content at 33.3°C	10.6
Solid Fat Content at 37.8°C	2.7
Solid Fat Content at 40.0°C	1.5

Typical Fatty Acid Profile, %

C8:0	3.5
C10:0	3.5
C12:0	47.4
C14:0	15.3
C16:0	8.3
C18:0	19.4
C18:1	2.6

Typical Chemical Properties

Moisture, ppm	100
Free Fatty Acid, % (as oleic)	0.04
Peroxide Value (PV), meq/kg	0
Iodine Value, Wijs	2.8
Saponification Value	244
RVOC, U.S. EPA, %	0

Nutritional Information (per 100 grams)

Total Calories	900
Calories from Fat at 9.0 cal/g	900
Total Fat, g	100
Saturated Fat, g	97.4
Monounsaturated Fat, g	2.6
Polyunsaturated Fat, g	0.0
Cholesterol, mg	0.0
Protein, g	0.0
Total Carbohydrate, g	0.0
Sugars, g	0.0
Dietary Fiber, g	0.0
Vitamin A, IU	0.0
Vitamin C, mg	0.0
Calcium, mg	0
Iron, mg	0
Sodium, mg	0

Biodegradability

Product is biodegradable. Additional information is available upon request.

Toxicity

WECOBEE FS has an LD_{50} >5 ml/kg and may cause minimal eye but no skin irritation.

March 2007
Supersedes:
July 2006

Storage & Handling	Normal safety precautions should be employed when handling WECOBEE FS. It is recommended that WECOBEE FS be stored in sealed containers at temperatures not exceeding 90°F (32°C). Avoid overheating . Standard Packaging: WECOBEE FS is available in 50 lb. cartons.
Clearances	WECOBEE FS is approved under FDA 21CFR 170.30 as GRAS. WECOBEE FS is Kosher Certified. All components of WECOBEE FS are listed in the chemical inventories of Europe, Korea, Canada and Australia.
FDA Status	WECOBEE FS has a Type IV Drug Master File (DMF) available.
Additional Safety Information	A Material Safety Data Sheet is available upon request.

Stepan

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March 2007
Supersedes:
July 2006

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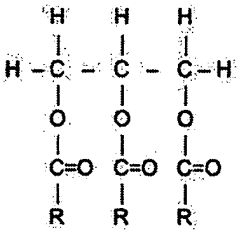
Product Bulletin FOOD & HEALTH SPECIALTIES

Product Name

WECOBEE® M

Chemical Structure



R = fatty acids from hydrogenated palm kernel oil

WECOBEE M is a triglyceride derived from vegetable oil.

CAS Registry No.

68334-28-1

Applications

- Cocoa butter replacement for confectionery coatings
- Dairy toppings and baked goods
- Base for suppositories and ointments

Typical Physical Properties

Appearance	White to off-white solid	Specific Gravity at 40°C	0.908
Odor and Flavor	Bland	Solid Fat Content at 10°C	95.1
Melting Point, °C (°F)	35 (95)	Solid Fat Content at 21.1°C	80.6
Smoke Point, °C (°F)	232.2 (450)	Solid Fat Content at 26.8°C	51.0
Flash Point, PMCC, °C (°F)	>282 (>540)	Solid Fat Content at 33.3°C	8.3
Viscosity, cSt at 40°C	35.8	Solid Fat Content at 37.8°C	0.0

Typical Fatty Acid Profile, %

C6:0	0.2	C14:0	15.7
C8:0	3.6	C16:0	8.6
C10:0	3.4	C18:0	20.9
C12:0	46.6	C18:1	0.8

Typical Chemical Properties

Moisture, ppm	200	Iodine Value, Wijs	1.2
Free Fatty Acid, % (as oleic)	0.04	Saponification Value	242
Peroxide Value (PV), meq/kg	0	RVOC, U.S. EPA, %	0

Nutritional Information (per 100 grams)

Total Calories	900	Total Carbohydrate, g	0.0
Calories from Fat at 9.0 cal/g	900	Sugars, g	0.0
Total Fat, g	100	Dietary Fiber, g	0.0
Saturated Fat, g	99.2	Vitamin A, IU	0.0
Monounsaturated Fat, g	0.8	Vitamin C, mg	0.0
Polyunsaturated Fat, g	0.0	Calcium, mg	1.0
Cholesterol, mg	0.0	Iron, mg	0.2
Protein, g	0.0	Sodium, mg	0.7

Biodegradability

Product is biodegradable. Additional information is available upon request.

Toxicity	WECOBEE M has an LD_{50} >5 ml/kg and may cause minimal eye but no skin irritation.
Storage & Handling	Normal safety precautions should be employed when handling WECOBEE M. It is recommended that WECOBEE M be stored in sealed containers at temperatures not exceeding 90°F (32°C). Avoid overheating. Standard Packaging: WECOBEE M is available in 50 lb cartons and 55 gallon drums (net weight 400 lb/181 kg).
Clearances	WECOBEE M is approved under FDA 21CFR 170.30 as GRAS. WECOBEE M is Kosher Certified. WECOBEE M conforms to the USP/NF monograph for Hard Fat. All components of WECOBEE M are listed in the following countries; the registration numbers of the active ingredients are included in parentheses: United States (TSCA 68334-28-1), Europe (EINECS 269-820-6), Korea (ECL Serial No. KE-20177), Canada (DSL 68334-28-1), Australia (AICS 68334-28-1), Philippines (PICCS 68334-28-1), Japan (ENCS 8-358) and China (EICS Part 1).
FDA Status	WECOBEE M has a Type IV Drug Master File (DMF) available.
Additional Safety Information	A Material Safety Data Sheet is available upon request. Nothing contained herein grants or extends a license, express or implied, in connection with patents, issued or pending, of the manufacturer or others. The information contained herein is based on the manufacturer's own study and the works of others. The manufacturer makes no warranties, expressed or implied, as to the accuracy, completeness, or adequacy of the information contained herein. The manufacturer shall not be liable (regardless of fault) to the vendee's employees, or anyone for any direct, special or consequential damages arising out of or in connection with the accuracy, completeness, adequacy or furnishing of such information.

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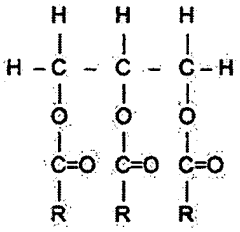
Product Bulletin FOOD & HEALTH SPECIALTIES

Product Name

WECOBEE® S

Chemical Structure



R = fatty acids from hydrogenated palm kernel and cottonseed oils

WECOBEE S is a triglyceride derived from vegetable oil.

CAS Registry No.

68334-28-1

Applications

- Cocoa butter replacement for confectionery coatings
- Dairy toppings and baked goods
- Base for suppositories and ointments

Typical Physical Properties

Appearance	White to off-white flakes
Odor and Flavor	Bland
Color, Lovibond	2 Red
Melting Point, °C (°F)	44 (111)
Density, g/mL (lbs/U.S. gal)	0.90 (7.5)
Smoke Point, °C (°F)	232.2 (450)
Melting Point, open in H_2O, °C (°F)	43.0 (109.4)
Flash Point, PMCC, °C (°F)	>282 (>540)
Solid Fat Content at 10°C	94.6
Solid Fat Content at 21.1°C	75.2
Solid Fat Content at 26.8°C	50.9
Solid Fat Content at 33.3°C	22.9
Solid Fat Content at 37.8°C	12.2
Solid Fat Content at 40.0°C	9.3

Typical Fatty Acid Profile, %

C6:0	0.2	C14:0	12.9
C8:0	3.7	C16:0	10.1
C10:0	3.4	C18:0	26.5
C12:0	39.5	C18:1	3.5

Typical Chemical Properties

Moisture, ppm	300	Iodine Value, Wijs	3.0
Free Fatty Acid, % (as oleic)	0.04	Saponification Value	240
Peroxide Value (PV), meq/kg	0	RVOC, U.S. EPA, %	0

Nutritional Information (per 100 grams)

Total Calories	900	Total Carbohydrate, g	0.0
Calories from Fat at 9.0 cal/g	900	Sugars, g	0.0
Total Fat, g	100	Dietary Fiber, g	0.0
Saturated Fat, g	96.5	Vitamin A, IU	0.0
Monounsaturated Fat, g	3.5	Vitamin C, mg	0.0
Polyunsaturated Fat, g	0.0	Calcium, mg	0.7
Cholesterol, mg	0.0	Iron, mg	0.1
Protein, g	0.0	Sodium, mg	0.7

March 2007
Supersedes:
July 2006

Biodegradability	Product is biodegradable. Additional information is available upon request.
Toxicity	WECOBEE S has an LD_{50} >5 ml/kg and may cause minimal eye but no skin irritation.
Storage & Handling	Normal safety precautions should be employed when handling WECOBEE S. It is recommended that WECOBEE S be stored in sealed containers at temperatures not exceeding 90°F (32°C). Avoid overheating. Standard Packaging: WECOBEE S is available in 15 gallon fiber drums (net weight 50 lb/22.7 kg).
Clearances	All components of WECOBEE S are listed in the following countries; the registration numbers for the active ingredients are included in parentheses: Europe (EINECS 269-820-6), Canada (DSL 68334-28-1), Australia (AICS 68334-28-1), Philippines (PICCS 68334-28-1), Korea (KE-20177), United States (TSCA 68334-28-1), Japan (ENCS 8-358) and China (EICS Part 1) WECOBEE S is approved under 21 CFR 170.30 as GRAS. WECOBEE S is also approved for use under FDA 21 CFR 175.105, 176.210.
FDA Status	WECOBEE S has a Type IV Drug Master File (DMF) available.

Additional Safety Information

A Material Safety Data Sheet is available upon request.

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Manila, Philippines +632-891-1708

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March 2007
Supersedes:
July 2006

Witepsol

Int. Cl.: 1

Prior U.S. Cl.: 6

United States Patent and Trademark Office

Renewal

Reg. No. 857,719
Registered Oct. 1, 1968
OG Date Mar. 21, 1989

TRADEMARK
PRINCIPAL REGISTER

WITEPSOL

HULS TROISDORF AKTIENGESELLSCHAFT (FED REP GERMANY CORPORATION)
POSTFACH 1165
TROISDORF, FED REP GERMANY, ASSIGNEE BY ASSIGNMENT AND CHANGE OF NAME CHEMISCHE WERKE WITTEN G.M.B.H. (FED REP GERMANY COMPANY) WITTEN, RUHR, FED REP GERMANY

FOR: PHARMACEUTICAL BASE MATERIALS—NAMELY, SUPPOSITORY MASSES CONSISTING PRINCIPALLY OF SATURATED FATTY ACID ESTERS OF GLYCERINE, IN CLASS 6 (INT. CL. 1).

FIRST USE 3-10-1959; IN COMMERCE 10-3-1960.

SER. NO. 132,112, FILED 9-26-1961.

In testimony whereof I have hereunto set my hand and caused the seal of The Patent and Trademark Office to be affixed on Mar. 21, 1989.

COMMISSIONER OF PATENTS AND TRADEMARKS

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This page was generated by the TARR system on 2007-12-07 10:55:30 ET

Serial Number: 72132112 Assignment Information Trademark Document Retrieval

Registration Number: 857719

Mark (words only): WITEPSOL

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 1989-02-09

Filing Date: 1961-09-26

Transformed into a National Application: No

Registration Date: 1968-10-01

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

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Date In Location: 2001-11-07

LAST APPLICANT(S)/OWNER(S) OF RECORD

1. HULS TROISDORF AKTIENGESELLSCHAFT

Address:
HULS TROISDORF AKTIENGESELLSCHAFT
POSTFACH 1165
TROISDORF
Fed Rep Germany
Legal Entity Type: Corporation
State or Country of Incorporation: Fed Rep Germany

GOODS AND/OR SERVICES

U.S. Class: 006 (International Class 001)
Class Status: Active
PHARMACEUTICAL BASE MATERIALS-NAMELY, SUPPOSITORY MASSES CONSISTING PRINCIPALLY OF SATURATED FATTY ACID ESTERS OF GLYCERINE
Basis: 1(a)
First Use Date: 1959-03-10
First Use in Commerce Date: 1960-10-03

ADDITIONAL INFORMATION

(NOT AVAILABLE)

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

1988-10-01 - First renewal

1988-09-19 - Section 9 filed/check record for Section 8

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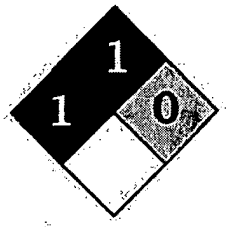

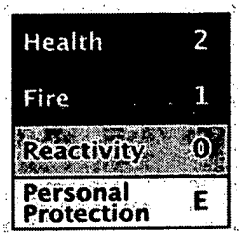

Material Safety Data Sheet
Witepsol MSDS

Section 1: Chemical Product and Company Identification

Product Name: Witepsol

Catalog Codes: SLW1078

CAS#: Not available.

RTECS: Not available.

TSCA: TSCA 8(b) inventory: No products were found.

CI#: Not available.

Synonym: Witepsol H 15 Pellets;

Chemical Name: Not available.

Chemical Formula: Not available.

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Witepsol contains:		100
Glycerides, C10-C18	85665-33-4	98
1,2,3-Propanetriol (Glycerol or Glycerin)	56-81-5	1
Fatty Acids, C10-C18	None	1

Toxicological Data on Ingredients: Witepsol LD50: Not available. LC50: Not available.

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of eye contact (irritant), of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: CLOSED CUP: >200°C (392°F).

Flammable Limits: Not available.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of open flames and sparks, of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available.
Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
If the product is in its solid form: Use a shovel to put the material into a convenient waste disposal container. If

the product is in its liquid form: Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. If you feel unwell, seek medical attention and show the label when possible.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 23°C (73.4°F).

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
TWA: 10 (mg/m3) from ACGIH (TLV) [United States] [Glycerol]
TWA: 15 (mg/m3) from OSHA (PEL) [United States] [Glycerol]
Consult local authorities for acceptable exposure limits.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Solid pellets.)

Odor: Not available.

Taste: Not available.

Molecular Weight: Not available.

Color: White.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: 34°C (93.2°F)

Critical Temperature: Not available.

Specific Gravity: 0.95 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Not available.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Not available.

Corrosivity: Not available.

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
LD50: Not available.
LC50: Not available.

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans:
Hazardous in case of ingestion.
Slightly hazardous in case of skin contact (irritant), of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: Causes skin irriation. Exposure is not expected to cause significant irritation or toxicity.
Eyes: Dust caused mechanical irritation.
Inhalation: Dust may cause irritation of the respiratory tract. Under normal use conditions, this product is not expected to pose a significant inhalation hazard.
Ingestion: Ingestion may cause gastrointestinal (digestive) tract irritation with discomfort, nausea, and vomiting.
No significant hazard expected under normal industrial use.
The toxicological properties of this substance have not been fully investigated.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: Not available.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: No products were found.

Other Regulations: Not available.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
R36- Irritating to eyes.
S2- Keep out of the reach of children.
S46- If swallowed, seek medical advice immediately and show this container or label.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Splash goggles.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 12:16 AM

Last Updated: 10/10/2005 12:16 AM

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PRODUCT INFORMATION

26.13.056e/09.99

Suppository Bases; Hard Fat, Adeps solidus, E

WITEPSOL ® is a white, odorless Hard Fat, consisting of glyceri

Chemical and Physical Characteristics

Type	Ascending melting point	Hydroxyl value	Iodine value	Peroxide value	Acid value	Sapo tion v
	°C	mg KOH/g	g I_2/100 g	mequl O/kg	mg KOH/g	mg K
Method	EP 2.2.15	EP 2.5.3	EP 2.5.4	EP 2.5.5	EP 2.5.1	EP 2.
WITEPSOL H 5	34.0 - 36.0	max. 5	max. 2	max. 1	max. 0.2	235 -
WITEPSOL H 12	32.0 - 33.5	5 - 15	max. 3	max. 1	max. 0.2	240 -

Lanolin

Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Lanolin

1. Nonproprietary Names

BP: Wool fat
JP: Purified lanolin
PhEur: Adeps lanae
USP: Lanolin

2. Synonyms

Cera lanae; E913; lanolina; lanolin anhydrous; *Protalan anhydrous*; purified lanolin; refined wool fat.

3. Chemical Name and CAS Registry Number

Anhydrous lanolin [8006-54-0]

4. Empirical Formula and Molecular Weight

The USP 28 describes lanolin as the purified wax-like substance obtained from the wool of the sheep, Ovis aries Linné (Fam. Bovidae), that has been cleaned, decolorized, and deodorized. It contains not more than 0.25% w/w of water and may contain up to 0.02% w/w of a suitable antioxidant; the PhEur 2005 specifies up to 200 ppm of butylated hydroxytoluene as an antioxidant.

See also Section 18.

5. Structural Formula

See Section 4.

6. Functional Category

Emulsifying agent; ointment base.

7. Applications in Pharmaceutical Formulation or Technology

Lanolin is widely used in topical pharmaceutical formulations and cosmetics.

Lanolin may be used as a hydrophobic vehicle and in the preparation of water-in-oil creams and ointments. When mixed with suitable vegetable oils or with soft paraffin, it produces emollient creams that penetrate the skin and hence facilitate the absorption of drugs. Lanolin mixes with about twice its own weight of water, without separation, to produce stable emulsions that do not readily become rancid on storage.

See also Section 18.

8. Description

Lanolin is a pale yellow-colored, unctuous, waxy substance with a faint, characteristic odor. Melted lanolin is a clear or almost clear, yellow liquid.

9. Pharmacopeial Specifications

See Table I.

10. Typical Properties

Autoignition temperature: 445°C

Density: 0.932–0.945 g/cm^3 at 15°C

Flash point: 238°C

Refractive index: n_D^{40} = 1.478–1.482

Solubility: freely soluble in benzene, chloroform, ether, and petroleum spirit; sparingly soluble in cold ethanol (95%), more soluble in boiling ethanol (95%); practically insoluble in water.

11. Stability and Storage Conditions

Lanolin may gradually undergo autoxidation during storage. To inhibit this process, the inclusion of butylated hydroxytoluene is permitted as an antioxidant. Exposure to excessive or prolonged heating may cause anhydrous lanolin to darken in color and develop a strong rancidlike odor. However, lanolin may be sterilized by dry heat at 150°C. Ophthalmic ointments containing lanolin may be sterilized by filtration or by exposure to gamma irradiation.[1]

Lanolin should be stored in a well-filled, well-closed container protected from light, in a cool, dry place. Normal storage life is 2 years.

12. Incompatibilities

Lanolin may contain prooxidants, which may affect the stability of certain active drugs.

13. Method of Manufacture

Lanolin is a naturally occurring wax-like material obtained from the wool of sheep, Ovis aries Linné (Fam. Bovidae).

Crude lanolin is saponified with a weak alkali and the resultant saponified fat emulsion is centrifuged to remove the aqueous phase. The aqueous phase contains a soap solution from which, on standing, a layer of

partially purified lanolin separates. This material is then further refined by treatment with calcium chloride, followed by fusion with unslaked lime to dehydrate the lanolin. The lanolin is finally extracted with acetone and the solvent is removed by distillation.

14. Safety

Lanolin is widely used in cosmetics and a variety of topical pharmaceutical formulations.

Although generally regarded as a nontoxic and nonirritant material, lanolin and lanolin derivatives are associated with skin hypersensitivity reactions and the use of lanolin in subjects with known sensitivity should be avoided.[2,3] Other reports suggest that 'sensitivity' arises from false positives in patch testing.[4] However, skin hypersensitivity is relatively uncommon;[5] the incidence of hypersensitivity to lanolin in the general population is estimated to be around 5 per million.[6]

Sensitivity is thought to be associated with the content of free fatty alcohols present in lanolin products rather than the total alcohol content.[7] The safety of pesticide residues in lanolin products has also been of concern.[8,9] However, highly refined 'hypoallergenic' grades of lanolin and grades with low pesticide residues are commercially available.[10] *See also* Section 18.

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16. Regulatory Status

Included in the FDA Inactive Ingredients Guide (ophthalmic, otic, topical, and vaginal preparations). Included in nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.

17. Related Substances

Cholesterol; hydrogenated lanolin; lanolin, hydrous; lanolin alcohols; modified lanolin.

See also Section 18.

Hydrogenated lanolin

Synonyms: adeps lanae hydrogenatus; hydrogenated wool fat.

Acid value: ≤1.0

Hydroxyl value: 140–180

Melting point: 45–55°C

Saponification value: ≤8.0

Water: ≤3.0%

Comments: some pharmacopeias, such as the PhEur 2005, contain a monograph for hydrogenated lanolin. This material is a mixture of higher aliphatic alcohols and sterols obtained from the direct, high-pressure, high-temperature hydrogenation of lanolin during which the esters and acids present are reduced to the corresponding alcohols. Hydrogenated lanolin may contain a suitable antioxidant; the PhEur 2005 specifies not more than 200 ppm of butylated hydroxytoluene.

Modified lanolin

Comments: some pharmacopeias, such as the USP 28, contain a monograph for modified lanolin. This material is lanolin that has been processed to reduce the contents of free lanolin alcohols and detergent and pesticide residues. It contains not more than 0.25% w/w of water. The USP 28 specifies that it may contain not more than 0.02% w/w of a suitable antioxidant.

18. Comments

Lanolin (the anhydrous material) may be confused in some instances with hydrous lanolin since the USP formerly contained monographs for 'lanolin' and 'anhydrous lanolin' in which the name 'lanolin' referred to the material containing 25–30% w/w of purified water. However, in the USP 28 the former lanolin monograph (hydrous lanolin) is deleted and the monograph for anhydrous lanolin is renamed 'lanolin'.

Since lanolin is a natural product obtained from various geographical sources, its physical characteristics such as color, consistency, iodine value, saponification value, and hydroxyl value may vary for the products from different sources. Consequently, formulations containing lanolin from different sources may also have different physical properties.

A wide range of grades of lanolin are commercially available that have been refined to different extents in order to produce hypoallergenic grades or grades with low pesticide contents.

Many lanolin derivatives are also commercially available that have properties similar to those of the parent material and include: acetylated lanolin; ethoxylated or polyoxyl lanolin (water-soluble); hydrogenated lanolin; isopropyl lanolate; lanolin oil; lanolin wax; liquid lanolin; and water-soluble lanolin.

A specification for anhydrous lanolin is contained in the Food Chemicals Codex (FCC), where it is described as being used as a masticatory substance in chewing gum base. The EINECS number for lanolin is 232-348-6.

19. Specific References

1. Smith GG, Fonner DE, Griffin JC. New process for the manufacture of sterile ophthalmic ointments. *Bull Parenter Drug Assoc* 1975; **29**: 18–25.(PubMed)

2. Anonymous. Lanolin allergy. *Br Med J* 1973; **2**: 379–380.(PubMed)

3. Breit J, Bandmann H-J. Dermatitis from lanolin. *Br J Dermatol* 1973; **88**: 414–416.(PubMed)

4. Kligman AM. The myth of lanolin allergy. *Contact Dermatitis* 1998; **39**: 103–107.(PubMed)

5. Wakelin SH, Smith H, White IR, *et al*. A retrospective analysis of contact allergy to lanolin. *Br J Dermatol* 2001; **145**(1): 28–31.(PubMed)

6. Clark EW. Estimation of the general incidence of specific lanolin allergy. *J Soc Cosmet Chem* 1975; **26**: 323–335.

7. Clark EW, Cronin E, Wilkinson DS. Lanolin with reduced sensitizing potential: a preliminary note. *Contact Dermatitis* 1977; **3**(2): 69–74.

8. Copeland CA, Raebel MA, Wagner SL. Pesticide residue in lanolin [letter]. *J Am Med Assoc* 1989; **261**: 242.

9. Cade PH. Pesticide residue in lanolin [letter]. *J Am Med Assoc* 1989; **262**: 613.

10. Steel I. Pure lanolin in treating compromised skin. *Manuf Chem* 1999; **70**(9): 16–17.

20. General References

Barnett G. Lanolin and derivatives. *Cosmet Toilet* 1986; **101**(3): 23–44.

Osborne DW. Phase behavior characterization of ointments containing lanolin or a lanolin substitute. *Drug Dev Ind Pharm* 1993; **19**: 1283–1302.

Smolinske SC. *Handbook of Food, Drug, and Cosmetic Excipients*. Boca Raton, FL: CRC Press, 1992: 225–229.

21. Authors

AJ Winfield.

22. Date of Revision

15 August 2005.

Lanolin

Lanolin, a grease from wool-bearing animals, acts as a skin ointment, water-proofing wax, and raw material.

Lanolin is "wool fat" or grease, chemically akin to wax, it is produced by wool-bearing animals such as sheep and is secreted by their sebaceous glands. These glands are associated with hair follicles. Lanolin acts as a waterproofing wax, and recent studies indicate that antibiotics are also present in the lanolin. It helps them to shed water from their coats. Certain breeds of sheep produce large amounts of lanolin and the extraction can be performed by squeezing the wool between rollers. Lanolin is used commercially in a great many products ranging from rust preventitive coatings to cosmetics. Most or all the lanolin is removed from wool when it is processed into textiles e.g. yarn or felt.

Lanolin is often used as a raw material for producing vitamin D3.

Medical grade lanolin is also used as a cream to sooth skin. Lansinoh cream, a product that some breastfeeding mothers use on sore and cracked nipples, is ultrapure, hypoallergenic, bacteriostatic medical grade lanolin. This grade of lanolin can also be used to treat chapped lips , diaper rash, dry skin, minor cuts, minor burns and skin abrasions.

External links

- Lansinoh and lanolin
- La Leche League International's stance on lanolin

Incromega

Int. Cl.: 1

Prior U.S. Cls.: 1, 5, 6, 10, 26 and 46

Reg. No. 2,054,931

United States Patent and Trademark Office

Registered Apr. 22, 1997

TRADEMARK
PRINCIPAL REGISTER

INCROMEGA

CRODA INC. (DELAWARE CORPORATION)
7 CENTURY DRIVE
PARSIPPANY, NJ 070544698

FOR: CHEMICAL ADDITIVES, NAMELY, FATTY ACIDS FOR USE IN THE MANUFACTURE OF PHARMACEUTICALS, COSMETICS, NUTRITIONAL SUPPLEMENTS AND FORTIFIED FOOD PRODUCTS, IN CLASS 1 (U.S. CLS. 1, 5, 6, 10, 26 AND 46).

FIRST USE 4-1-1993; IN COMMERCE 4-1-1993.

SER. NO. 75-090,548, FILED 4-18-1996.

RONALD MCMORROW, EXAMINING ATTORNEY

Thank you for your request. Here are the latest results from the TARR web server.

This page was generated by the TARR system on 2007-12-07 11:01:28 ET

Serial Number: 75090548 Assignment Information Trademark Document Retrieval

Registration Number: 2054931

Mark (words only): INCROMEGA

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2007-03-28

Filing Date: 1996-04-18

Transformed into a National Application: No

Registration Date: 1997-04-22

Register: Principal

Law Office Assigned: LAW OFFICE 105

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 830 -Post Registration

Date In Location: 2007-03-28

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. CRODA INC.

Address:
CRODA INC.
300 COLUMBUS CIRCLE
EDISON, NJ 088373907
United States
Legal Entity Type: Corporation
State or Country of Incorporation: Delaware

GOODS AND/OR SERVICES

International Class: 001
Class Status: Active
chemical additives, namely, fatty acids for use in the manufacture of pharmaceuticals, cosmetics, nutritional supplements and fortified food products
Basis: 1(a)
First Use Date: 1993-04-01
First Use in Commerce Date: 1993-04-01

ADDITIONAL INFORMATION

(NOT AVAILABLE)

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2007-03-28 - First renewal 10 year

2007-03-28 - Section 8 (10-year) accepted/ Section 9 granted

2007-03-27 - Assigned To Paralegal

2007-02-09 - Combined Section 8 (10-year)/Section 9 filed

2007-02-09 - PAPER RECEIVED

2006-12-13 - Case File In TICRS

2006-09-05 - Review Of Correspondence Complete

2003-08-27 - PAPER RECEIVED

2003-05-29 - Section 8 (6-year) accepted & Section 15 acknowledged

2003-01-27 - Section 8 (6-year) and Section 15 Filed

2003-01-27 - PAPER RECEIVED

1997-04-22 - Registered - Principal Register

1997-01-28 - Published for opposition

1996-12-27 - Notice of publication

1996-11-01 - Approved for Pub - Principal Register (Initial exam)

1996-10-23 - Examiner's amendment mailed

1996-09-18 - Assigned To Examiner

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Correspondent
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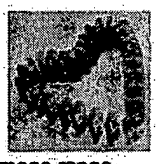
LERNER, DAVID, ET AL.
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090-1497

Nutritional

Our ranges of ultra pure marine and plant oils, proteins and peptides have been designed to meet the demands of the growing markets for condition-specific dietary supplements and functional foods.

- **Incromega marine oil concentrates**
- **Crossential plant oils and concentrates**
- **Nutritional proteins and peptides**

Incromega marine oil concentrates



The **Incromega** range is a new generation of omega-3 marine oil concentrates that offer enhanced bioavailability and potency for specific conditions. The lipids are manufactured using **PureMax**, Croda's advanced purification and concentration technology. With a minimum of 3 molecular distillation steps, PureMax selectively concentrates the key fatty acid actives, EPA and/or DHA, whilst removing impurities. Compliant with PhEur and CRN monographs the Incromega range includes:

Key product ranges	Applications
Incromega TG7010 SR Incromega E7010 SR	Feeling stressed, tired, rundown, depressed? Enhance your mood with the Incromega 7010 range.
Incromega TG6015 Incromega EPA500TG SR	Problems with joint inflammation or arthritic pain? Perfect lubrication for the 50+ generation.
Incromega E400200 SR Incromega E4010	Feed a child's brain and enhance their concentration. Cost effective EPA supplementation for the health conscious parent.
Incromega DHA700TG SR Incromega DHA700E SR	Pregnant or lactating? Maximum DHA for you and your baby.
Incromega DHA500TG SR	Develop your eyes and brain, whatever the age. DHA is the smart ingredient.
Incromega TG3322 SR Incromega E3322 SR	A fishy business? Not any more. Now use the omega 3 benefits
Incromega TG3322 Incromega E3322	Containing 60% LCPUFA, the first true concentrates for general well being. The first omega 3 concentrate to contain EPA, DPA
Incromega Trio TG/EE	The first omega 3 concentrate to contain EPA, DPA and DHA. Take control of your heart with the power of three.

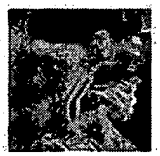
Crossential plant oils and concentrates

Crossentials are naturally derived plant lipids including omega-3, -6 and -9 unsaturated fatty acids. They are manufactured using Croda's proprietary concentration and Super Refining technology and are available as high purity free fatty acids, ethyl esters and triglycerides.

Key products	Description	Functions/applications
Crossential EPO TG25	Evening Primrose Oil	Atopic eczema, PMS, diabetic neuropathy
Crossential GLA TG40	Borage Oil	Atopic eczema, PMS, diabetic neuropathy
Crossential SA14	Echium Plantaginium	Anti-inflammatory active, anti-wrinkle and skin smoothing properties, vegetable source of EPA

Nutritional proteins and peptides

Croda offers high quality specialty proteins for convenience health food products, such as protein bars and sports drinks. They provide a rich source of natural amino acids, including glutamine, glycine, arginine, proline and two which are unique to collagen.



Key products	Description	Functions/applications
Procol	Hydrolysed marine, bovine or porcine gelatins	Nutritional bars, slimming foods & sports nutrition

For more detailed product information, please contact us using our on-line enquiry form

Product summary

Request more information

Incromega DHA 500TG SR
High purity DHA (Docosahexaenoic acid) concentrate - triglyceride

Details:

General Chemical Name:	Docosahexaenoic acid concentrate
PhEur Monograph::	Omega-3 Acid Triglycerides
USP/NF Monograph:	-
EINECS:	309-181-3

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Liquid
Molecular weight:	-
HLB:	-

Benefits / Properties:

- Purer concentration of individual DHA (500 mg/g)
- High bioavailability
- Greater activity
- Very low peroxide and para-anisidine values
- Excellent taste and odour
- Low level of trace impurities

Applications:

- Dietary supplements - maternal nutrition, infant eye, brain and nervous system development
- Clinical nutrition
- Disease management
- Functional foods
- Pharmaceuticals

Product summary

Request more information

Incromega DHA700E SR

New high potency DHA concentrate offering 700mg/g of DHA – produced using advanced concentration and purification technologies and specifically designed to maximise the therapeutic benefits of this particular lipid

Details:

General Chemical Name:	Docosahexaenoic acid concentrate
PhEur Monograph::	Omega-3 Acid Ethyl Esters 60
USP/NF Monograph:	-
EINECS:	309-181-3

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Clear pale yellow liquid
Molecular weight:	-
HLB:	-

Benefits / Properties:

- High potency DHA concentrate (min 700 mg/g)
- EPA levels minimised (max 120 mg/g)
- Targets specific conditions more effectively
- Allows smaller and fewer capsules per DHA dose
- Encourages greater patient compliance
- Ph Eur compliant
- Excellent taste, odour and colour
- Low level of trace impurities
- Low peroxide and para-anisidine values

Applications:

- Maternal supplementation for infant brain, eye and general development
- Eye health
- Cognitive function in elderly
- Depression
- Dyslexia, ADHD and dyspraxia
- Central nervous system disorders

Product summary

Request more information

Incromega E3322
High omega-3 polyunsaturated fatty acid concentrate - ethyl ester

Details:

General Chemical Name:	Omega-3 polyunsaturated fatty acid concentrate
PhEur Monograph::	Omega-3 Acid Ethyl Esters
USP/NF Monograph:	-
EINECS:	293-054-1

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Topical, Oral
Appearance:	Liquid
Molecular weight:	-
HLB:	-

Benefits / Properties:

- Cost-effective omega-3 PUFA concentrate
- High total omega-3 PUFA concentration (min 65%)
- 33% min EPA and min 22% DHA
- Contains 10% more EPA and DHA than competing products
- Purified using Croda's unique molecular distillation process
- Low levels of trace impurities eg heavy metals and pesticides
- Low levels of oxidation products (low peroxide and para-anisidine values)
- European Pharmacopoeia compliant (EP Supplement 2000)
- High omega-3 concentration allows reduced capsule size
- Lower calories per dose than standard fish oil
- Low cholesterol levels

Applications:

- Dietary supplements
- Functional foods

Product summary

Request more information

Incromega E4010
EPA (Eicosapentaenoic acid) concentrate - ethyl ester

Details:

General Chemical Name:	Eicosapentaenoic acid concentrate
PhEur Monograph::	-
USP/NF Monograph:	-
EINECS:	293-054-1

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Liquid
Molecular weight:	-
HLB:	-

Benefits / Properties:

- Cost-effective EPA concentrate
- High EPA (min 40%) and low DHA (max 10%) concentrations
- Purified using Croda's unique molecular distillation process
- Low levels of oxidation products (low peroxide and para-anisidine values)
- Low levels of trace impurities eg heavy metals and pesticides
- High EPA concentration allows reduced capsule size
- Lower calories per dose than standard fish oil

Applications:

- Dietary supplements - cardiovascular and inflammatory disorders eg rheumatoid arthritis, psoriasis
- Functional foods

Product summary

Incromega E7010 SR
New high potency EPA concentrate offering 70% EPA – produced using advanced concentration and purification technologies and specifically designed to maximise the therapeutic benefits of this particular lipid

Details:

General Chemical Name:	Eicosapentaenoic acid concentrate
PhEur Monograph::	Omega-3-Acid Ethyl Esters 60
USP/NF Monograph:	-
EINECS:	

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Clear pale yellow liquid
Molecular weight:	-
HLB:	-

Request more information

Benefits / Properties:

- High potency EPA concentrate (min 70%)
- DHA levels minimised (max15%)
- Targets specific conditions more effectively
- Allows smaller and fewer capsules per EPA dose
- Encourages greater patient compliance
- Ph Eur compliant
- Excellent taste, odour and colour
- Low level of trace impurities
- Low peroxide and para-anisidine values

Applications:

- Mood disorders (schizophrenia, bipolar disorder)

Product summary

Request more information

Incromega EPA500TG SR
High purity EPA (Eicosapentaenoic acid) concentrate - triglyceride

Details:

General Chemical Name:	Eicosapentaenoic acid concentrate
PhEur Monograph::	Omega-3 Acid Triglycerides
USP/NF Monograph:	-
EINECS:	309-181-3

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Liquid
Molecular weight:	-
HLB:	-

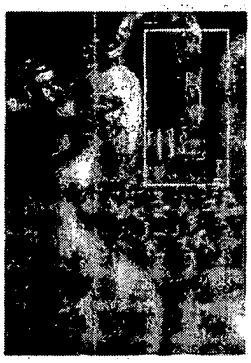
Benefits / Properties:

- Purer concentration of individual EPA (500 mg/g)
- High bioavailability
- Greater activity
- Very low peroxide and para-anisidine values
- Excellent taste and odour
- Low level of trace impurities

Applications:

- Dietary supplements - cardiovascular and inflammatory disorders eg rheumatoid arthritis, psoriasis
- Clinical nutrition
- Disease management
- Functional foods
- Pharmaceuticals

Product summary



Incromega FD3322
High omega-3 polyunsaturated fatty acid concentrate - free fatty acid

Details:

General Chemical Name:	Omega-3 polyunsaturated fatty acid concentrate
PhEur Monograph::	-
USP/NF Monograph:	-
EINECS:	234-245-1

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Liquid
Molecular weight:	-
HLB:	-

Benefits / Properties:

- High total omega-3 PUFA concentration (min 60%)
- 33% min EPA and 22% min DHA
- 10% more EPA and DHA than competing products
- Triglyceride is the natural form of omega-3 long chain PUFAs
- High bioavailability
- Purified using Croda's unique molecular distillation process
- Low levels of trace impurities eg heavy metals and pesticides
- Low levels of oxidation products (low peroxide and para-anisidine values)
- European Pharmacopoeia compliant
- Certificate of Suitability (RO-CEP 2000-233-Rev 00)
- High omega-3 concentrations allow reduced capsule size
- Lower calories per dose than standard fish oil
- Low cholesterol levels

Applications:

- Dietary supplements
- Functional foods

Product summary

Request more information

Incromega Trio EE
The first selectively enhanced marine oil containing EPA, DPA and DHA

Details:

General Chemical Name:	Omega-3 polyunsaturated fatty acid concentrate
PhEur Monograph::	Omega-3 Acid Ethyl Esters
USP/NF Monograph:	
EINECS:	293-054-1

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Liquid
Molecular weight:	-
HLB:	-

Benefits / Properties:

- High potency salmon oil concentrate
- Min 55% total omega-3
- 15% EPA, 7.5% DPA, 30% DHA
- Strong consumer appeal
- Smaller and fewer capsules per omega 3 dose
- Encourages greater consumer compliance
- Industry-leading purity profile
- Condition-specific performance
- PhEur & CRN compliant
- Also available in triglyceride form

Applications:

- Dietary supplements, specifically targetted at cardiovascular care and wellbeing.
- Clinical nutrition
- Medicinal foods
- Pharmaceuticals

Product summary

Request more information

Incromega Trio TG
The first selectively enhanced marine oil containing EPA, DPA and DHA

Details:

General Chemical Name:	Omega-3 polyunsaturated fatty acid concentrate
PhEur Monograph::	Omega-3-acid triglycerides
USP/NF Monograph:	-
EINECS:	309-181-3

Properties:

Chemical group:	Omega-3 fatty acids
Application category:	Oral
Appearance:	Liquid
Molecular weight:	-
HLB:	-

Benefits / Properties:

- High potency salmon oil concentrate
- Min 55% total omega-3
- 15% EPA, 7.5% DPA, 30% DHA
- Strong consumer appeal
- Smaller and fewer capsules per omega 3 dose
- Encourages greater consumer compliance
- Industry-leading purity profile
- Condition-specific performance
- PhEur & CRN compliant
- Also available in ethyl ester form

Applications:

- Dietary supplements, specifically targetted at cardiovascular care and wellbeing.
- Clinical nutrition
- Medicinal foods
- Pharmaceuticals

Estaram

Int. Cls.: 1 and 3

Prior U.S. Cls.: 6, 18, 51 and 52

United States Patent and Trademark Office

Reg. No. 1,613,416
Registered Sep. 18, 1990

TRADEMARK
PRINCIPAL REGISTER

ESTARAM

DS INDUSTRIES APS (DENMARK CORPORATION)
ISLANDS BRYGGE 24
COPENHAGEN S., DENMARK

FOR: OIL-BASED INGREDIENTS USED IN THE MANUFACTURE OF COSMETICS; OIL-BASED PREPARATION FOR USE IN THE MANUFACTURE OF PHARMACEUTICAL FORMULATIONS FOR HUMAN AND VETERINARY PURPOSES, SUPPOSITORIES AND DIETETIC SUBSTANCES , IN CLASS 1 (U.S. CLS. 6, 18, 51 AND 52).

FOR: ESSENTIAL OILS USED AS INGREDIENTS IN THE MANUFACTURE OF COSMETICS, IN CLASS 3 (U.S. CL. 51).

PRIORITY CLAIMED UNDER SEC. 44(D) ON DENMARK APPLICATION NO. VA05926/1987, FILED 9-4-1987, REG. NO. VR07484/1989, DATED 12-1-1989, EXPIRES 12-1-1999.

SER. NO. 73-710,454, FILED 2-5-1988.

FRED MANDIR, EXAMINING ATTORNEY

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Serial Number: 73710454 Assignment Information Trademark Document Retrieval

Registration Number: 1613416

Mark (words only): ESTARAM

Standard Character claim: No

Current Status: Registration canceled under Section 8.

Date of Status: 1997-03-24

Filing Date: 1988-02-05

Transformed into a National Application: No

Registration Date: 1990-09-18

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 900 -File Repository (Franconia)

Date In Location: 1993-12-17

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. DS INDUSTRIES APS

Address:
DS INDUSTRIES APS
ISLANDS BRYGGE 24
COPENHAGEN S.
Denmark
Legal Entity Type: Corporation
State or Country of Incorporation: Denmark

GOODS AND/OR SERVICES

1990-03-23 - Approved for Pub - Principal Register (Initial exam)

1990-03-06 - Communication received from applicant

1989-12-28 - Inquiry as to suspension mailed

1989-06-20 - Letter of suspension mailed

1989-05-01 - Communication received from applicant

1988-11-02 - Letter of suspension mailed

1988-10-11 - Communication received from applicant

1988-05-31 - Non-final action mailed

1988-04-15 - Assigned To Examiner

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NEW YORK, NY 10017

Domestic Representative
WEISS DAWID FROSS ZELNICK & LEHRMAN

Suppoweiss

SUPOWEISS B 9121

Features and Benefits

Feature	Benefit

Typical Properties

Physical characteristic	Value
Acid value(Maximum)	0.20 mgKOH/g
Iodine value(Maximum)	1.0 g/100g

The above data represents typical global values for the properties shown. This is not a specification. Specifications from different regional manufacturing sites may not be identical.

Applications

Pharmaceutical

Functional Effects

Storage Condition

Recommended Usage

UNIQEMA

For further information please contact us below:

Europe

Uniqema, Wilton Centre, Wilton, Redcar TS10 4RF, UK
Tel: +44 1642 456 699. Fax +44 1642 435344.

Americas

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Tel: +1 888 424 3696 or +1 302 574 5000 Fax +1 302 574 1790.

Asia

Uniqema Asia Pacific, Lot 1 Solok Waja 3,
Bukit Raja Industrial Estate, 1710 Klang, Selangor, Malaysia.
Tel: +603 3349 2015. Fax: +603 3343 1923.

www.uniqema.com

Gelucire

Int. Cl.: 1

Prior U.S. Cls.: 1, 6 and 18

Reg. No. 1,345,393

United States Patent and Trademark Office Registered July 2, 1985

TRADEMARK
PRINCIPAL REGISTER

GELUCIRE

ETABLISSEMENTS GATTEFOSSE (FRANCE CORPORATION)
36, CHEMIN DE GENAS
SAINT PRIES, FRANCE 69800

FOR: RAW MATERIALS FOR USE IN THE PHARMACEUTICAL INDUSTRY AS EXDIPIENTS FOR HARD GELATIN CAPSULES, IN CLASS 1 (U.S. CLS. 1, 6 AND 18).

FIRST USE 0-0-1978; IN COMMERCE 0-0-1982.

OWNER OF FRANCE REG. NO. 1,153,123, DATED 4-30-1980, EXPIRES 4-30-1990.

OWNER OF U.S. REG. NO. 934,777.

SER. NO. 442,741, FILED 9-7-1983.

ROBERT RABINOWITZ, EXAMINING ATTORNEY

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Serial Number: 73442741 Assignment Information Trademark Document Retrieval

Registration Number: 1345393

Mark (words only): GELUCIRE

Standard Character claim: No

Current Status: This registration has been renewed.

Date of Status: 2005-06-13

Filing Date: 1983-09-07

Transformed into a National Application: No

Registration Date: 1985-07-02

Register: Principal

Law Office Assigned: (NOT AVAILABLE)

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 830 -Post Registration

Date In Location: 2005-06-13

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. GATTEFOSSE SAS

Address:
GATTEFOSSE SAS
36 Chemin de Genas
69800 Saint-Priest
France
Legal Entity Type: Joint Stock Company
State or Country Where Organized: France

GOODS AND/OR SERVICES

International Class: 001
Class Status: Active
Raw Materials for Use in the Pharmaceutical Industry as Exdipients for Hard Gelatin Capsules
Basis: 1(a)
First Use Date: 1978-00-00
First Use in Commerce Date: 1982-00-00

ADDITIONAL INFORMATION

Prior Registration Number(s):
934777

Foreign Registration Number: 1,153,123
Foreign Registration Date: 1980-04-30
Country: France
Foreign Expiration Date: 1990-04-30

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2005-06-13 - First renewal 10 year

2005-06-13 - Section 8 (10-year) accepted/ Section 9 granted

2005-06-13 - Assigned To Paralegal

2005-05-24 - Combined Section 8 (10-year)/Section 9 filed

2005-05-24 - Attorney Revoked And/Or Appointed

2005-05-24 - TEAS Revoke/Appoint Attorney Received

2005-05-24 - TEAS Section 8 & 9 Received

1991-07-06 - Section 7 amendment issued

1991-06-10 - Section 8 (6-year) accepted & Section 15 acknowledged

1991-03-04 - Response received for Post Registration action

1990-12-04 - Post Registration action mailed Section 8 & 15

1990-08-13 - Section 8 (6-year) and Section 15 Filed

1990-08-13 - Section 8 (6-year) and Section 15 Filed

1985-07-02 - Registered - Principal Register

1985-04-23 - Published for opposition

1985-03-28 - Notice of publication

1984-09-07 - Approved for Pub - Principal Register (Initial exam)

1984-07-26 - Communication received from applicant

1984-04-02 - Non-final action mailed

1984-03-15 - Assigned To Examiner

ATTORNEY/CORRESPONDENT INFORMATION

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Correspondent
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3735 Concord Road
Doylestown PA 18901

Domestic Representative
Janet G. Ricciuti

Probe into the Physical Properties of a Gelucire® 44/14 Pharmaceutical Formulation

H. Elmaleh, C.Neves, M.-A.Perrin

Aventis Pharma, 13 quai Jules Guesde, 94403 Vitry sur Seine, France

The number of poorly bioavailable drugs developed by the pharmaceutical industry has considerably increased during the last few years. Different approaches to overcoming the problem are currently being used. One way is to disperse the drug substance (DS) in a surface-active carrier in order to enhance its bioavailability; this is commonly called solid dispersion. This study will address the physical characterization of a Gelucire®-based solid dispersion formulation and illustrate some of its potential drawbacks in terms of DS physical stability.

Gelucire® 44/14 is a semi-solid excipient frequently used in the pharmaceutical industry. It is a mixture of glycerol and PEG1500 esters of long fatty acids. The suffixes 44 and 14 refer respectively to its melting point and its hydrophilic/lypophilic balance (HLB). A conventional manufacturing process consists in melting Gelucire® at 60°C and then incorporating the DS. The mixture is then homogenized and poured into gelatin capsules.

The DS used here is a well-crystallized monohydrate, denoted form A. As it dehydrates at 90°C, this crystalline form's thermal stability makes it suitable for a Gelucire® formulation. Nevertheless, attempts to manufacture this formulation failed. When the DS was incorporated into the liquid Gelucire®, there was a rapid increase in the viscosity of the mixture, leading to complete solidification, which made it impossible to pour the preparation into the capsules. Decreasing the operating temperature and/or the DS concentration to optimize the process did not solve the problem. In order to account for this phenomenon, a physical characterization of both the mixture and its individual components was carried out using X-ray powder diffraction (XRPD), high temperature XRPD, differential scanning calorimetry (DSC), hot stage microscopy (HSM) and water sorption/desorption.

It is a particular combination of the physico-chemical characteristics of form A and Gelucire® that caused the formulation process to fail. Gelucire® is highly hygroscopic under high-temperature conditions. Form A dissolves immediately in water, and a few minutes later the solution gels completely. Studies using microscopy and XRPD revealed that gelling proceeds from the hair-like morphology recrystallization into a new crystalline form of DS (a dihydrate), denoted form B. Thus, when form A is incorporated into liquid Gelucire®, a fraction of it dissolves in the water taken up by the Gelucire®, subsequently crystallizing into hair-like crystals (form B) and causing the heated mixture to gel.

During the manufacturing process, the heating & cooling rates, holding time at high temperature, the presence of water in the carrier, and the mechanical stirring can all induce important physical transformations of the DS crystals, such as solubilization, hydration/dehydration, phase transition, recrystallization.... As in-process physical monitoring is very difficult to perform, analysis is usually done at the end of the manufacturing process. Therefore, information concerning the evolution of the physical state of the DS in situ is generally inaccessible. Investigation of the physical state of the DS in the formulated product during processing and its stability over time still remains a major challenge.

The Comparative Toxicogenomics Database™

Chemicals: gelucire 44-14

Basic Information

Name	**gelucire 44-14**
Chemical Synonym	PEG-32 glyceryl laurate
CAS Registry No.	121548-04-7
Usage Note	*This information is provided for research and educational purposes.* ***We do not sell chemicals.***

In the News

	Chemical	Article	Publisher	Year
1.	Polyethylene Glycols	Are pesticide "inerts" an unrecognized environmental danger?	*Environmental Science & Technology*	2005

Hierarchies

Path 1: Chemicals > Organic Chemicals > Alcohols > Glycols > Ethylene Glycols > Polyethylene Glycols

gelucire 44-14	

= Curated interaction data available. = Disease data available. = Microarray data available.

The Comparative Toxicogenomics Database™

Chemicals: Gelucire 50-02

Basic Information

Name	**Gelucire 50-02**
Chemical Synonym	G 50-02
CAS Registry No.	125622-72-2
Usage Note	*This information is provided for research and educational purposes.* ***We do not sell chemicals.***

Hierarchies

[Jump to: Path 1 | Path 2 | Term Information]

Path 1: Chemicals > Lipids > Fats

Gelucire 50-02	

[Jump to: Path 1 | Path 2 | Term Information]

Path 2: Chemicals > Lipids > Oils

Gelucire 50-02	

= Curated interaction data available. = Disease data available. = Microarray data available.

The Comparative Toxicogenomics Database™

Chemicals: Gelucire 50-13

Basic Information

Name	**Gelucire 50-13**
Chemical Synonym	G 50-13
CAS Registry No.	121548-05-8
Usage Note	*This information is provided for research and educational purposes.* ***We do not sell chemicals.***

Hierarchies

[Jump to: Path 1 | Path 2 | Term Information]

Path 1: Chemicals > Lipids > Fats

Gelucire 50-13	

[Jump to: Path 1 | Path 2 | Term Information]

Path 2: Chemicals > Lipids > Oils

Gelucire 50-13	

= Curated interaction data available. = Disease data available. = Microarray data available.

GELUCIRE® 44/14

Chemical name : Lauroyl macrogolglycerides (polyoxylglycerides)
Physical appearance : Waxy solid
Melting point : 44°C
HLB Value : 14

Regulatory status :

Food					Pharma		
FCC	GRAS	USFA	European food additive	JSFA	EP	USP-NF	FDA II
		✓			✓	✓	

Applications

Gelucire® 44/14 is a semi-solid excipient that is proven to greatly improve the poorly-soluble drugs.
It can be used in a variety of formulation techniques (granules and tablets) and it rem of choice for formulation in capsules.
It can be used alone or as part a self emulsifying formulation.

Oral dosage forms					Functions		
Tablets	Chewable tablets	Soft capsules	Hard capsules	Oral liquid formulations	Bioavailability enhancer	Sustained release agent	Taste-masking agent
✓		✓	✓		✓		

Documentation Request - Close

® **Brand registered in :** FRANCE, USA

GELUCIRE® 50/13

Chemical name : Stearoyl macrogolglycerides (polyoxylglycerides)
Physical appearance : Waxy solid in pellets
Melting point : 50°C
HLB Value : 13

Regulatory status :

Food					Pharma		
FCC	GRAS	USFA	European food additive	JSFA	EP	USP-NF	FDA II
		✓			✓	✓	✓

Applications

Gelucire® 50/13 is a semi-solid excipient that is proven to improve the bioavai soluble drugs.
It can be used in a variety of formulation techniques (granules and tablets) and it rem of choice for formulation in capsules.
Formulated in capsule **Gelucire® 50/13** will confer a slow release profile due to its hi When used in granulation or other combined approaches, it delivers an immediate rele its high HLB.

2

Oral dosage forms					Functions		
Tablets	Chewable tablets	Soft capsules	Hard capsules	Oral liquid formulations	Bioavailability enhancer	Sustained release agent	Taste-masking agent
✓		✓	✓		✓	✓	

Documentation Request - Close

® **Brand registered in :** FRANCE, USA

Precirol

Int. Cl.: 5

Prior U.S. Cls.: 6, 18, 44, 46, 51 and 52

United States Patent and Trademark Office

Reg. No. 3,004,129

Registered Oct. 4, 2005

TRADEMARK
PRINCIPAL REGISTER

PRECIROL

GATTEFOSSE SAS (FRANCE JOINT STOCK COMPANY)
36 CHEMIN DE GENAS
69800 SAINT-PRIEST, FRANCE

FOR: PHARMACEUTICAL PRODUCTS NOTABLY PHARMACEUTICAL EXCIPIENTS, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

PRIORITY CLAIMED UNDER SEC. 44(D) ON ERPN CMNTY TM OFC APPLICATION NO. 3838539, FILED 5-21-2004, REG. NO. 3838539, DATED 5-21-2004, EXPIRES 5-21-2014.

SER. NO. 78-443,138, FILED 6-29-2004.

THEODORE MCBRIDE, EXAMINING ATTORNEY

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Serial Number: 78443138 Assignment Information Trademark Document Retrieval

Registration Number: 3004129

Mark

PRECIROL

(words only): PRECIROL

Standard Character claim: Yes

Current Status: Registered.

Date of Status: 2005-10-04

Filing Date: 2004-06-29

Transformed into a National Application: No

Registration Date: 2005-10-04

Register: Principal

Law Office Assigned: LAW OFFICE 103

If you are the applicant or applicant's attorney and have questions about this file, please contact the Trademark Assistance Center at TrademarkAssistanceCenter@uspto.gov

Current Location: 650 -Publication And Issue Section

Date In Location: 2005-10-04

LAST APPLICANT(S)/OWNER(S) OF RECORD

---

1. Gattefosse SAS

Address:
Gattefosse SAS
36 Chemin de Genas
69800 Saint-Priest
France
Legal Entity Type: Joint Stock Company
State or Country Where Organized: France

GOODS AND/OR SERVICES

International Class: 005
Class Status: Active
Pharmaceutical products notably pharmaceutical excipients
No Filing Basis Claimed

First Use Date: (DATE NOT AVAILABLE)
First Use in Commerce Date: (DATE NOT AVAILABLE)

ADDITIONAL INFORMATION

Foreign Application Number: 3838539
Foreign Registration Number: 3838539
Foreign Registration Date: 2004-05-21
Country: Erpn Cmnty TM Ofc
Foreign Filing Date: 2004-05-21
Foreign Expiration Date: 2014-05-21

MADRID PROTOCOL INFORMATION

(NOT AVAILABLE)

PROSECUTION HISTORY

NOTE: To view any document referenced below, click on the link to "Trademark Document Retrieval" shown near the top of this page.

2005-10-04 - Registered - Principal Register

2005-07-12 - Published for opposition

2005-06-22 - Notice of publication

2005-04-06 - Law Office Publication Review Completed

2005-04-01 - Assigned To LIE

2005-03-30 - Approved for Pub - Principal Register (Initial exam)

2005-02-09 - Amendment From Applicant Entered

2004-09-22 - Communication received from applicant

2005-02-08 - Previous allowance count withdrawn

2005-02-07 - Approved for Pub - Principal Register (Initial exam)

2005-02-03 - Assigned To Examiner

2004-09-22 - PAPER RECEIVED

2004-07-07 - New Application Entered In Tram

ATTORNEY/CORRESPONDENT INFORMATION

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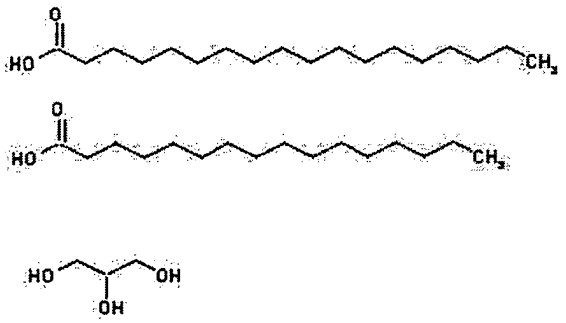
3735 CONCORD RD
DOYLESTOWN PA 18901-5444

Domestic Representative
Janet G. Ricciuti

The Comparative Toxicogenomics Database™

Chemicals: precirol

Basic Information

Name	**precirol**
CAS Registry No.	8067-32-1
Chemical Drawing	
Usage Note	*This information is provided for research and educational purposes.* ***We do not sell chemicals.***

Hierarchies

Path 1: Chemicals > Lipids > Glycerides > Diglycerides

precirol

= Curated interaction data available. = Disease data available. = Microarray data available.

Emulcire

SpecialChem Cosmetics
Innovation & Solutions in

Emulcire® 61

General Information

Trade	Emulcire
Grade	Emulcire® 61
Producer	Gattefosse
Chemical Name	
CAS Number	

Appearance	Pellets

CTFA/INCI Name	Cetyl Alcohol, Ceteth-20, Steareth-20.

Functional Ingredient

- emulsifiers >> emulsifiers o/w(oil in water)

End Application

- skin care (facial care, facial cleansing, body care, baby care)
- skin care (facial care, facial cleansing, body care, baby care) >> body care >> hand creams & lotions
- toiletries (shower & bath, oral care, hand washing, antiperspirants, depilatory products, shaving, foot care) >> depilatories & after depilation
- hair care (shampoos, conditioners & styling) >> treatment products

Comments

Allows the formation of stable emulsions in the presence of difficult-to-use additives. Can be used alone or in combinaison with Superpolystate. For creams with an excellent heat stability. Used in hands creams with a high percentage of glycerine and AHA products.

Quantitative Properties

Chemical product information

KREGLINGER

We are one of the largest Belgian traders, distributors (exclusive, non-exclusive), for chemicals and allied products, cosmetics, ingredients and pharmaceuticals worldwide

Started in 1951 under the name Ets George Arion, this business was acquired by Plouvier & Kreglinger in 1985 (since 1998, G & C Kreglinger). In 1998, Ets George Arion merged with Cy Chemical Products Delahaye and became Arion & Delahaye s.a. End of 2002, operations were restructured under the KREGLINGER EUROPE s.a.

We distribute in Belgium / Grand Duchy of Luxembourg / the Netherlands, United

EMULCIRE® **61**

Physical appearance : Pellets

Cetyl Alcohol (and) Ceteth-20 (and) Steareth-20

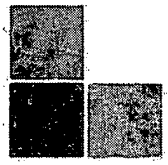
O/W emulsifier for creams. Allows the formulation of stable emulsions in the presence of difficult-to-use actives (depilatories, AHAs, hair relaxers, hand creams with a high percentage of glycerin...). Provides excellent heat stability. Can be used alone or in combination with SUPERPOLYSTATE.

www.gattefosse.com

Purpose(s) :
emulsifier

Kingdom and France. Some products are also distributed in other European countries.

Contact for more information



THE NETHERLANDS >>

Printer-friendly product specifications

Direct link http://www.kreglinger.com/eng/

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Cosmetics & Personal Care Catalogue - Emulsifiers

Please note this is by no means a complete list of our emulsifiers.
For more information please Contact Us.

Emulsifier Product Catalogue
Select a product below to review more information.

back to top | new search

Name	**Apifil**
INCI Name	PEG-8 Beeswax
Physical Form	Pellets
Function/Description	emulsifier for creams or lotions, excellent co lipophilic ingredients and inorganic powders
Applications	makeup, skin care, sun care
Usage Levels (%)	

back to top

Name	**Emulcire 61**
INCI Name	Cetyl Alcohol (and) Ceteth-20 (and) Stearet
Physical Form	Pellets
Function/Description	allows the formulation of stable emulsions in actives, provides excellent heat stability

Applications	hair care, skin care, toiletries
Usage Levels (%)	2-6
back to top	request sample

Name	**Emulfree CBG**
INCI Name	Isostearyl Alcohol (and) Butylene Glycol Coc
Physical Form	Liquid
Function/Description	innovative emulsifier-free and PEG-free syst cosmetic oils, recommended for sensitive sk
Applications	hair care, makeup, skin care, sun care, toilet
Usage Levels (%)	
back to top	request sample

Name	**Emulfree P**
INCI Name	Propylene Glycol Laurate (and) Ethylcellulos Isostearate
Physical Form	Liquid
Function/Description	innovative oil-based emulsifier-free and PEG compatibility with medium to high polarity oil recommended for sensitive skin products
Applications	hair care, makeup, skin care, sun care, toilet
Usage Levels (%)	1-6
back to top	request sample

Name	**Emulium 22**
INCI Name	Tribehenin PEG-20 Esters
Physical Form	Pellets
Function/Description	emulsifier for creams and lotions, provides th spreadability and comfort during application,
Applications	hair care, makeup, skin care, sun care
Usage Levels (%)	
back to top	request sample

Name	**Emulium Delta**
INCI Name	Cetyl Alcohol (and) Glyceryl Stearate (and) I 20 (and) Steareth-20
Physical Form	Pellets
Function/Description	emulsifier for creams, adapted to most cosm crystal structure
Applications	hair care, skin care, sun care, toiletries
Usage Levels (%)	
back to top	request sample

Physical Form	Pellets
Function/Description	emulsifier dedicated to hair care products, pi creams, recommended for the design of con and colouring products
Applications	hair care, skin care, sun care, toiletries
Usage Levels (%)	

back to top

request sample

Plurol diisostearique

SpecialChem Cosmetics
Innovation & Solutions in

Plurol® Diisostearique

General Information

Trade	Plurol
Grade	Plurol® Diisostearique
Producer	Gattefosse
Chemical Name	
CAS Number	

Appearance	Liquid

CTFA/INCI Name	Polyglyceryl-3 Diisostearate

Functional Ingredient

- emulsifiers >> emulsifiers o/w(oil in water)

End Application

- skin care (facial care, facial cleansing, body care, baby care)
- skin care (facial care, facial cleansing, body care, baby care) >> baby care
- decorative cosmetics/make-up
- sun care (sun protection, after-sun & self-tanning)

Comments

PEG-free. Allows the formulation of cold-processed emulsions. Can be used alone (creams) or in combinaison with Plurol Oleique (lotions). Mascaras. For dry skin.

Quantitative Properties

chemidex®

The Formulator's Search Engine™

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Personal Care & Cosmetics > Latin America

PLUROL DIISOSTEARIQUE

by Gattefossé - USA

A triglyceryl diisostearate that is used as a water-in-oil emulsifier.

View more details on PLUROL DIISOSTEARIQUE
Document for PLUROL DIISOSTEARIQUELogin|Register to view
Brochure

- Plurol Diisostearique: An Advanced Approach To Continuous Oil Phases (English)
- TEXTURES: THE ART OF FORMULATION (English)

Data Sheet

- Data Sheet (English)

MSDS

- MSDS (English)

Formulations for PLUROL DIISOSTEARIQUELogin|Register to view

- Baby Care Cream (Formulation #MM 4896)
- Water-In-Oil Foundation Cream (Formulation #MS 0085)
- Water-In-Oil Hair Care Cream (Formulation #MM 4861/B)
- Water-In-Oil Moisturizing Cream (Formulation #PL 2696/C)
- Water-In-Oil Semi Fluid Lotion - Mineral Oil Free (Formulation #PL 2748/A)
- Water-In-Oil Sunscreen Cream (Formulation #MS 0124)

Product PropertiesLogin|Register to view
Chemical Content

- Ash
- Heavy Metals

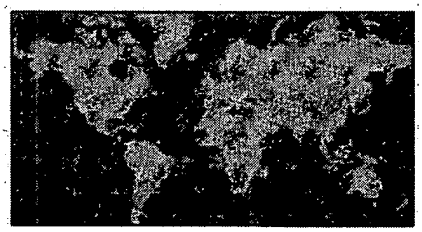
- Water/Moisture

Physical

- Acid Number
- Appearance
- CAS #
- Color, Gardner
- INCI Name
- Iodine Number
- Odor
- Peroxide Value
- Refractive Index
- Saponification Value
- Solubility
- Stability - Shelf Life (Months)

Company
View all products from

- Gattefossé - USA Latin America, Personal Care & Cosmetics



Language
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- Industry Information

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25, ceteth-25; self-emulsifying cosmetic base
Hydrophilol ISO [Gattefosse SA] Propylene glycol isostearate; CAS 68171-38-0; superfatting agent
Isostearate Isostearyle [Gattefosse] Isostearyl isostearate; CAS 41669-30-1; emollient, excipient
Labrafac® CC [Gattefosse; Gattefosse SA] Caprylic/capric triglyceride; CAS 65381-09-1; excipient, oily vehicle
Labrafac® Hydro WL 1219 [Gattefosse; Gattefosse SA] Caprylic/capric triglycerides PEG-4 esters; hydrophilic cosmetic/pharmaceutical oil, solubilizer, surfactant
Labrafac® Hydrophile [Gattefosse; Gattefosse SA] Caprylic/capric triglyceride PEG-4 complex; bioavailability enhancer, emulsifier, solvent, solubilizer
Labrafac® Lipophile [Gattefosse; Gattefosse SA] Caprylic/capric triglyceride; CAS 65381-09-1; excipient, vehicle
Labrafac® Lipophile WL 1349 [Gattefosse] Caprylic/capric triglyceride; CAS 65381-09-1; superfatting agent
Labrafac PC [Gattefosse] Propylene glycol caprylate/caprate; excipient, amphiphilic oil, permeation enhancer, coemulsifier
Labrafil® Isostearique [Gattefosse; Gattefosse SA] Triisostearin PEG-6 esters; hydrophilic oil, solvent, excipient
Labrafil® M 1944 CS [Gattefosse; Gattefosse SA] Apricot kernel oil PEG-6 esters; CAS 97488-91-0; hydrophilic oil, coemulsifier, bioavailability enhancer, excipient
Labrafil® M 1969 CS [Gattefosse; Gattefosse SA] Peanut oil PEG-6 esters; CAS 68440-49-3; hydrophilic oil
Labrafil® M 1980 CS [Gattefosse; Gattefosse SA] Olive oil PEG-6 esters; CAS 103819-46-1; hydrophilic oil
Labrafil® M 2125 CS [Gattefosse; Gattefosse SA] Corn oil PEG-6 esters; CAS 61789-25-1; solubilizer, bioavailability enhancer, coemulsifier
Labrafil® M 2130 BS [Gattefosse; Gattefosse SA] Hydrogenated palm/palm kernel oil PEG-6 esters; hydrophilic wax
Labrafil® M 2130 CS [Gattefosse; Gattefosse SA] Palm kernel oil, palm oil, PEG-6, and hydrogenated palm/palm kernel oil PEG-6 esters; hydrophilic wax, excipient, coemulsifier, thickener
Labrafil® WL 2609 BS [Gattefosse] Corn oil PEG-8 esters; CAS 61789-25-1; bioavailability enhancer, emulsifier, excipient, solubilizer
Labrasol® [Gattefosse; Gattefosse SA] PEG-8 caprylic/capric glycerides; CAS 85536-07-8; solvent, excipient, solubilizer
Lactofil [Gattefosse] Lactose and milk protein; cosmetic ingred.
L.A.S. [Gattefosse SA] PEG-8 caprylic/capric glycerides; CAS 85536-07-8; excipient
Lauroglycol® 90 [Gattefosse SA] Propylene glycol monolaurate; CAS 142-55-2; solubilizer
Lauroglycol® FCC [Gattefosse] Propylene glycol laurate; CAS 142-55-2; excipient, coemulsifier, carrier, solubilizer
Lipocire A [Gattefosse SA] Hydrogenated palm glycerides, hydrogenated palm kernel glycerides; lipstick base
Lipocire CM [Gattefosse SA] Hydrogenated palm glycerides, hydrogenated palm kernel glycerides; lipstick base
Lipocire DM [Gattefosse SA] Hydrogenated palm glycerides, hydrogenated palm kernel glycerides; lipstick base
Maisine® 35-1 [Gattefosse; Gattefosse SA] Glyceryl monolinoleate; CAS 2277-28-3; excipient, vehicle, solubilizer
Maisine® FCC [Gattefosse; Gattefosse SA] Glyceryl linoleate; CAS 2277-28-3; excipient, vehicle
M.O.D. [Gattefosse; Gattefosse SA] 2-Octyldodecyl myristate; CAS 22766-83-2; emollient, excipient
Monosteol® [Gattefosse; Gattefosse SA] Propylene glycol monostearate; CAS 1323-39-3; emulsifier, stabilizer, excipient
Monthybase [Gattefosse] Glycol stearate SE; CAS 86418-55-5; self-emulsifying base for o/w emulsions
Monthyle® [Gattefosse; Gattefosse SA] Glycol stearate; CAS 111-60-4; emulsifier, stabilizer, consistency enhancer, excipient
Neptuline® C [Gattefosse SA] Soluble collagen; moisturizing film-former
Olepal ISO [Gattefosse SA] PEG-6 isostearate; CAS 56002-14-3; solvent
Olicine [Gattefosse; Gattefosse SA] Peanut glycerides; CAS 91744-77-3; food emulsifier
Ovucire WL 2944 [Gattefosse SA] Hemisynthetic glycerides; excipient
Pancogene® Marine [Gattefosse] Soluble collagen; moisturizer for dry skin
Pancogene® S [Gattefosse] Soluble collagen; humectant
Peceol® [Gattefosse; Gattefosse SA] Glyceryl oleate; CAS 111-03-5; pharmaceutical excipient; vehicle
Peceol Isostearique [Gattefosse SA] Glyceryl isostearate; CAS 32057-14-0; surfactant, superfatting agent, excipient
Phylderm® Vegetal C [Gattefosse] Hydrolyzed soy protein; CAS 68607-88-5; cosmetic raw material
Plurol® Diisostearique [Gattefosse SA] Polyglyceryl-3 diisostearate; CAS 66082-42-6; emulsifier
Plurol® Isostearique [Gattefosse SA] Polyglyceryl-6 isostearate; CAS 126928-07-2; emulsifier
Plurol® Oleique [Gattefosse SA] Polyglyceryl-6 dioleate; CAS 76009-37-5; emulsifier, solubilizer
Plurol® Oleique CC 497 [Gattefosse SA] Polyglyceryl-6 oleate; CAS 9007-48-1; emulsifier, solubilizer, vehicle, thickener
Plurol® Stearique WL 1009 [Gattefosse SA] Polyglyceryl-6 distearate; CAS 34424-97-0; excipient, consistency agent, stabilizer
Polystate C [Gattefosse; Gattefosse SA] PEG-6 stearate; CAS 9004-99-3; self-emulsifying cosmetic base
Precifac ATO [Gattefosse SA] Cetyl palmitate; CAS 540-10-3; excipient, tableting agent and lipophilic matrix
Precirol ATO 5 [Gattefosse SA] Tripalmitin and tristearin; excipient, tableting agent, binder, lubricant
Precirol WL 2155 ATO [Gattefosse; Gattefosse SA] Glyceryl ditristearate; CAS 8067-32-1; tableting agent, excipient
Sedefos 75® [Gattefosse; Gattefosse SA] Glycol stearate, PEG-2 stearate, and trilaneth-4 phosphate; self-emulsifying cosmetic/pharmaceutical base
SMEDDS® [Gattefosse SA] Blends of excipients, surfactants, cosurfactants, a lipid phase, and an act. compd.; drug delivery system
Solubilisant γ 2420 [Gattefosse] Octoxynol-11, polysorbate 20; solubilizer
Solubilisant γ 2428 [Gattefosse] PEG-40 hydrogenated castor oil, polysorbate 20, octoxynol-11; solubilizer
Stearate 1500 [Gattefosse SA] PEG (1500) palmitostearate; solvent, emulsifier
Sucro Ester 7 [Gattefosse SA] Saccharose distearate; CAS 27195-16-0; food emulsifier, wetting agent, crystallization inhibitor
Sucro Ester 11 [Gattefosse SA] Saccharose mono/distearate; food emulsifier, wetting agent, crystallization inhibitor
Superpolystate® [Gattefosse SA] PEG-6 stearate SE; CAS 9004-99-3; self-emulsifying gelling cosmetic/pharmaceutical base
Suppocire® A [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® AI [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® AIM [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® AIML [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® AM [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® AML [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® AP [Gattefosse SA] Saturated polyglycolized glycerides; excipient, suppository base
Suppocire® AS2 [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® AS2X [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® B [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® BM [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® BML [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® BP [Gattefosse SA] Saturated polyglycolized glycerides; excipient, suppository base
Suppocire® BS2 [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® BS2X [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® C [Gattefosse SA] Semisynthetic glycerides; excipient, suppository base
Suppocire® CM [Gattefosse SA] Hydrogenated palm glycerides, hydroge-

Int. Cl.: 1

Prior U.S. Cls.: 1, 5, 6, 10, 26 and 46

Reg. No. 2,008,652

United States Patent and Trademark Office

Registered Oct. 15, 1996

TRADEMARK
PRINCIPAL REGISTER

PLUROL

GATTEFOSSE S.A. (FRANCE JOINT STOCK COMPANY)
36 CHEMIN DE GENAS
69800 SAINT-PRIEST, FRANCE

FOR: POLYGLYCEROL ESTERS, IN CLASS 1 (U.S. CLS. 1, 5, 6, 10, 26 AND 46).

FIRST USE 7-0-1993; IN COMMERCE 7-0-1993.

SER. NO. 75-025,973, FILED 12-1-1995.

ALEXANDER L. POWERS, EXAMINING ATTORNEY

PLUROL® DIISOSTEARIQUE

Chemical name : Polyglyceryl diisostearate
Physical appearance : Viscous liquid
HLB Value : 4.5

Food					Pharma		
FCC	GRAS	USFA	European food additive	JSFA	EP	USP-NF	FDA II
					✓		

Applications

Plurol ® Diisostearique is a W/O PEG-free emulsifier.
Used at concentrations ranging from 3% to 6%, it forms very stable creams with high and a light non-greasy texture and easy spreadabilityelegant with firm texture.
This product is highly recommended for thermosensitive drugs and can be used in methods.

Topical formulations		Functions						
Creams and lotions	Micro-emulsions and gels	Emulsifying base	Thickening agent	Emollient	Penetration enhancer	Solubilizer	Surfactant	sui
✓		✓						

Documentation Request - Close

Geleol

hibitor, surfactant
Aqualox® 236 [Gateway Addit.] Amine carboxylate; lubricant, corrosion inhibitor
Aqualox® 240 [Gateway Addit.] Amine carboxylate; surfactant, corrosion inhibitor
Aqualox® 242HT-90 [Gateway Addit.] Amine salt of org. acids; corrosion inhibitor, hydrotrope
Aqualox® 2268 [Gateway Addit.] Corrosion inhibitor, lubricant
Aqualox® 2295 [Gateway Addit.] Rust preventive conc.
Aqualox® 2320 [Gateway Addit.] Corrosion inhibitor, lubricant
Aqualox® 2328 [Gateway Addit.] Corrosion inhibitor, lubricant
Aqualox® 2500 [Gateway Addit.] Corrosion inhibitor, emulsifier
Becrosan® 2128A [Gateway Addit.] Arylsulfonamido carboxylic acid; corrosion inhibitor intermediate
Bio-Base GT-9000 [Gateway Addit.] Sodium sulfonate, branch chained sat. ester as sec. emulsifier; emulsifier base, antimicrobial, corrosion inhibitor, lubricant
Bio-Base GT-9001 [Gateway Addit.] Borated sodium sulfonate, branch chained sat. ester as sec. emulsifier; emulsifier, lubricant, dispersant
Olicat® C [Gateway Addit.] Polyisobutylene in mineral oil; tackiness agent, lubricant
Semi-Synthetic Base 2550 [Gateway Addit.] Base, lubricant, corrosion inhibitor, wetting agent
Semi-Synthetic Base 2590 [Gateway Addit.] Base, lubricant, corrosion inhibitor, wetting agent
Soluble Base GT-1150 [Gateway Addit.] Mixt. of high m.w. sodium sulfonate, sec. emulsifier system, and coupling agents; emulsifier base, lubricant, corrosion inhibitor
Soluble Base GT-1500 [Gateway Addit.] Mixt. of sodium sulfonate, sec. emulsifier; emulsifier base, lubricant, corrosion inhibitor
Soluble Base GT-1700VN [Gateway Addit.] Mixt. of sodium sulfonate, sec. emulsifier system, and coupling agents; emulsifier base, corrosion inhibitor
Soluble Base GT-1700VP [Gateway Addit.] Mixt. of sodium sulfonate, sec. emulsifier system, and coupling agents; emulsifier base, corrosion inhibitor
Syn-Ester® GY-10 [Gateway Addit.] High m.w. polymerized ester; lubricant, EP agent
Syn-Ester® GY-15 [Gateway Addit.] High m.w. polymerized ester; lubricant, EP agent
Syn-Ester® GY-16 [Gateway Addit.] Syn. high m.w. polymerized ester; sec. emulsifier
Syn-Ester® GY-25 [Gateway Addit.] High m.w. polymerized ester; lubricant, EP agent
Syn-Ester® GY-35 [Gateway Addit.] Syn. polymerized ester; sec. emulsifier
Syn-Ester® GY-201 [Gateway Addit.] High m.w. syn. branched chain saturated ester; EP agent, lubricant, corrosion inhibitor
Syn-Ester® GY-301 [Gateway Addit.] Syn. ester; coemulsifier, wetting agent
Syn-Ester® GY-500 [Gateway Addit.] Polymerized ester; lubricant, visc. index improver
Syn-Ester® GY-HTO [Gateway Addit.] High m.w. polymerized ester; EP agent, lubricant, corrosion inhibitor
Syn-Ester® SE-110 [Gateway Addit.] Sulfurized polymerized ester; lubricant, EP agent
Syn-Ester® SE-115 [Gateway Addit.] Sulfurized polymerized ester; lubricant, EP agent
Syn-Ester® SE-120 [Gateway Addit.] Sulfurized polymerized ester; lubricant, EP agent
Synthetic Micro-Emulsion ST-3100 [Gateway Addit.] Water-extendible base; lubricant

Gattefossé

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Gattefosse (UK) Ltd., Arc House, Terrace Rd. South, Binfield, Bracknell, Berkshire, RG42 4PZ, UK (Tel: 44 1344 86 18 00; FAX 44 1344 45 14 00)

Gattefossé Italia s.r.l., Via Derganino 20, 20158 Milan, Italy (Tel: 39 2 39 31 40 73; FAX 39 2 66 200 440; E-mail: cperego@gattefosse.it)

Gattefossé España, S.A., Avda. Diagonal 460, 6°A, 08006 Barcelona, Spain (Tel: 34 93 416 05 20; FAX 34 93 415 35 46)

Gattefosse Corp., 650 From Rd., Paramus, NJ, 07652, USA (Tel: 201-265-4800; FAX 201-265-4853; E-mail: gcsamples@gattefossecorp.com; Internet: www.gattefosse.com)

Gattefosse Canada, Inc., 711 Devon Pl., Baie d'Urfe, Quebec, H9X 2T3, Canada (Tel: 514-457-0921; FAX 514-457-0922; E-mail: jasminep@gattefosseca.com)

Gattefossé Korea, # 1403 Sung Ji Heights III 642-6, Yuksamdong, Kangnamgu, Seoul, 135-080, Korea (Tel: 82 2 508 3877; FAX 82 2 568 0425)

Trade Names:
Antistatique WL 879 [Gattefosse] Sorbitan caprylate; antistat
Apifil® [Gattefosse; Gattefosse SA] PEG-8 beeswax; emulsifier, moisturizer
Atowax [Gattefosse] Atomized beeswax; excipient, polishing agent, emulsion stabilizer, stiffening agent
Brillance 515 [Gattefosse] Apricot kernel oil PEG-6 esters and ethylcellulose; cosmetic ingred.
Capryol® PGMC [Gattefosse SA] Propylene glycol monocaprylate; CAS 31565-12-5; solubilizer
Cetasal [Gattefosse] Propylene glycol stearate, stearic acid, TEA-stearate, sulfated castor oil; gelifying, self-emulsifying base for o/w creams
Compricoat [Gattefosse] PEG-20 behenate; excipient, coating agent, emulsifier, solubilizer, wetting agent
Compritol 888 [Gattefosse; Gattefosse SA] Tribehenin; CAS 18641-57-1; excipient, lubricant
Compritol® 888 ATO [Gattefosse; Gattefosse SA] Tribehenin; CAS 18641-57-1; food emulsifier, excipient, lubricant, binder
Compritol HD5 ATO [Gattefosse; Gattefosse SA] PEG-8 behenate and tribehenin; excipient, lubricant, viscosifier, stiffening and brightening agent
D.P.P.G. [Gattefosse SA] Propylene glycol dipelargonate; CAS 41395-83-9; emollient
Emulcire 61 [Gattefosse; Gattefosse SA] Cetyl alcohol, ceteth-20, and steareth-20; self-emulsifying base
Emulium® Delta [Gattefosse] Cetyl alcohol, glyceryl stearate, PEG-75 stearate, ceteth-20, steareth-20; emulsifier
Fondix G Bis [Gattefosse SA] Propylene glycol, sodium methylparaben, sodium dehydroacetate, sorbic acid, tetrasodium EDTA; cosmetic preservative
Gatuline® A [Gattefosse SA] Pilewort (Ranunculus ficaria) extract; CAS 84929-74-8; skin treatment
Geleol® [Gattefosse; Gattefosse SA] Glyceryl stearate; CAS 31566-31-1; emulsifier, opacifier, excipient
Gelot 64® [Gattefosse; Gattefosse SA] Glyceryl stearate and PEG-75 stearate; self-emulsifying cosmetic/pharmaceutical base; excipient
Gelucire 33/01 [Gattefosse SA] Glycerol esters of sat. C8-C18 fatty acids USP/NF; excipient, carrier, vehicle, antioxidant
Gelucire 37/02 [Gattefosse SA] Saturated polyglycolized glycerides; excipient
Gelucire 39/01 [Gattefosse] Glycerol esters of sat. C12-C18 fatty acids; excipient, vehicle, consistency agent, fatting agent, antioxidant
Gelucire 43/01 [Gattefosse] Glycerol esters of sat. C12-C18 fatty acids; excipient, vehicle, consistency fatting agent
Gelucire 44/14 [Gattefosse SA] PEG-32 glyceryl laurate EP; excipient, solubilizer, emulsifier
Gelucire 50/02 [Gattefosse SA] Saturated polyglycolized glycerides; excipient
Gelucire 50/13 [Gattefosse SA] PEG-32 glyceryl palmitostearate; excipient
Gelucire 53/10 [Gattefosse SA] PEG-32 glyceryl stearate; excipient
Hydrine® [Gattefosse; Gattefosse SA] PEG-2 stearate; CAS 9004-99-3; thickener, gellant, stabilizer
Hydrolactol 70 [Gattefosse; Gattefosse SA] Glyceryl stearate, propylene glycol stearate, glyceryl isostearate, propylene glycol isostearate, oleth-

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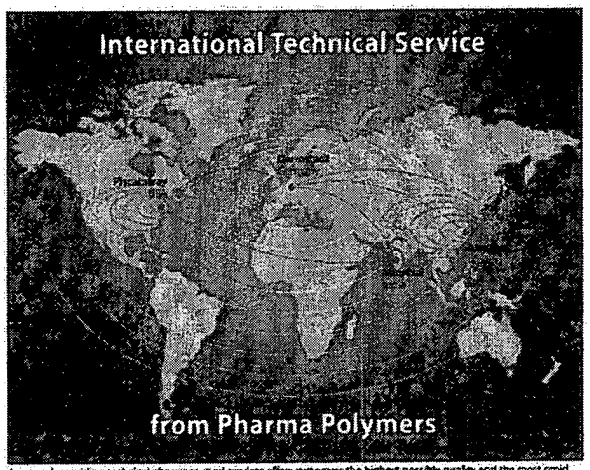
PHARMA POLYMERS
NEWS

No. 11 · ISSUE 2004

Technical Service Centers

Global Network Serves International Clientele

Globalization has affected companies, markets and forms of business. Today, international companies demand constantly available services in addition to high-quality products. To function independently around the globe, Pharma Polymers offers its customers a network of Technical Service Labs.



A network providing technical pharmaceutical services offers customers the highest possible quality and the most rapid solutions for their business — anywhere in the world.

The pharmaceutical market continues to become a more global business. Not only are the traditionally known multinational companies expanding into other markets, but regional companies are rapidly expanding internationally. This globalization creates a need for consistent and effective technical support as projects may move from development to scale-up in different parts of the world. In response to this emerging need for efficient global support, Pharma Polymers has built local expertise with knowledge of the relevant customer structures and business cultures in China, Japan and India, as well as reinforcing presence in the European and US markets. "Our presence is being expanded and strengthened to provide rapid and reliable solutions in the regions where customers themselves are doing business," clarifies Dr. Randy Bull, Global Business Manager for EUDRAGIT®. "We have been delivering our customers quality for a long time now by providing the best possible products and expertise for modified release oral dosage form applications. Now we can offer even more: services and projects for and in partnership with our customers provided by our sites worldwide, along with support and consulting." According to Dr. Brigitte Skalsky, who has managed the Technical Service Center in Darmstadt for the past two years, "Our strength in global business is our ability to provide scalable services – to small companies without their own laboratories, as well as to major international corporations."

Global business, regional support

While major pharmaceutical companies are global players, they operate via regional branches, which in turn work closely together on international projects. "Think globally, act locally" applies perfectly to Pharma Polymers. "Our global network of technical laboratories enables us to support our customers in any pharmaceutical market," explains Randy Bull, "while being assured of support and services at the same high level of quality anywhere in the world. We can assist in product development in one region and support scale-up in another using local resources in each case."

These services include a routine support service, development and production troubleshooting, and customer-tailored projects, such as drug product development, formulation modifications, feasibility studies, process optimization and scale-up/technology transfer up to the clinical preparations stage under GMP conditions, as well as a wide range of analytical services. Each partnership is customized to the client's application with development meetings and milestone scheduling to ensure that the project runs transparently just as planned.

From individual sites to worldwide network

It has taken Pharma Polymers just a few years to build this network of laboratories to complement laboratory facilities operated by business partners in key countries.

Operating for over 50 years in Darmstadt, Germany, the Pharma Polymers Technical Service Center moved into new laboratories equipped with ultramodern pharmaceutical equipment and analytical facilities in 2001, including a GMP facility for production of clinical supplies. The German head office, which has been positioned as a capable partner to the pharmaceutical industry for decades, can now offer an expanded range of services to customers worldwide.

Pharma Polymers branches abroad were established in Asia starting in 1998. The current hub of the company's activities there is the laboratory in Shanghai, dedicated in 2004 under the auspices of the new Degussa Technical Center Shanghai. Another lab was just opened in Tokyo, and a second development team is being set up in Mumbai, India. Peter Wolff, Regional Manager Asia/Pacific, explains the strategic importance of the region: "Asia is a key growth market for our business line and the entire Group. Japan is the second largest pharmaceutical market in the world, and we are working in direct proximity to major customers."

Established in 2002, the US branch in Piscataway, New Jersey, has since attained a prominent standing on the American market. Located in strategic proximity to major pharmaceutical companies, the modern laboratory there focuses on applications technology. "In addition to full-service customer support, we conduct research projects on sustained-release applications and coating processes," explains Lab Manager Dr. Nasser Nyamweya, "and we also offer application technology workshops for the benefit of our customers, just like the Darmstadt site."

World-class service – anywhere in the world

All of the laboratories in the Pharma Polymers network use the same basic equipment for developing, producing and analytically characterizing pharmaceutical products with EUDRAGIT®. The technical equipment and documentation comply with national standards and are in line with facilities typically employed by customers. Lab teams the world over work with the same proven processes and regularly exchange information. This global structure enables customers to benefit greatly from accelerated product development and reduced development expenses. The primary strength of Pharma Polymers today according to Randy Bull is "the ability to rapidly provide customers with our entire range of high-quality products and services on-site."

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Taste Masking by Ionic Interaction of EUDRAGIT® Polymer and Active Substance during Melt Extrusion

A New Approach to Taste Masking

Taste masking is an important objective in drug formulation, particularly for oral formulations containing drugs with an unpleasant taste. Tablets are frequently coated with a film to prevent any contact with the tongue but Pharma Polymers has a new, different approach to such 'bitter' problems.

Nobody wants to swallow nasty-tasting medicine, even if they think it may do them good. This is often the reason why patients show poor compliance with medication.

One way to avoid this problem is to coat tablets with a protective film. This approach, using the gastrosoluble polymer EUDRAGIT® E PO, was described in the 2003 issue of Pharma Polymers News, and is even effective for active substances, such as paracetamol, that dissolve rapidly.

Taste Masking by Ionic Interaction

If the active substance contains a carboxyl or amino group, another approach can be taken. Mixing it with a suitably chosen EUDRAGIT® polymer during melt extrusion causes an ionic interaction that is highly effective in masking the taste of the active substance (Figure 1).

This ionic interaction takes place without the need for water, or any other solvent, and occurs when the active substance and the polymer are melted together during the extrusion process. This procedure makes it possible to take advantage of both the solubility-promoting effect of the melt extrusion process and the taste-masking effect of ionic interaction.

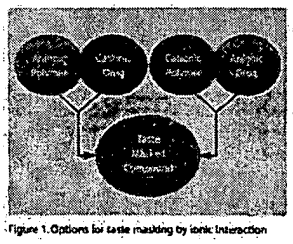

Figure 1. Options for taste masking by ionic interaction

If the active substance is cationic, an anionic polymer (e. g. EUDRAGIT® L 100-55, which contains carboxyl groups) should be chosen; if the active substance is anionic, then the cationic polymer EUDRAGIT® E (which has aminoalkyl groups) should be used, in each case mixed in equimolar proportion with the active substance.

The Melt Extrusion Process

Melt extrusion is a well-established granulation method, with a number of advantages for large-scale manufacturing. It is easily controlled, continuous, and solvent-free, and it has a high throughput capacity, resulting in cost-effective production (Figure 2).

In this process, the active substance and polymer are filled into separate hoppers and fed into a twin-screw extruder, where they are melted together at a temperature between 70°C and 140°C, and then kneaded to a homogeneous mixture. This is extruded as a fine strand, which is subsequently cooled and granulated.

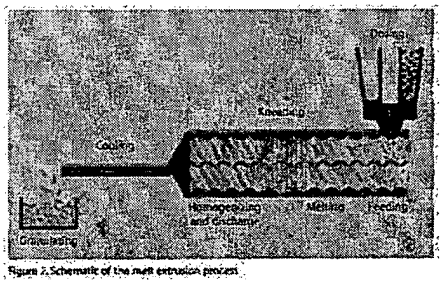

Figure 2. Schematic of the melt extrusion process

Testing the Taste-Masking Principle

Taste masking by ionic interaction between active substance and EUDRAGIT® polymers has been demonstrated in a series of pilot-scale experiments. Ibuprofen, which is a bitter active substance with a free carboxyl (anionic) group, was chosen as the test substance and coextruded with the cationic (aminoalkyl) polymer EUDRAGIT® E 100. Three different polymer/ibuprofen mixtures were tested, with molar ratios of 1:0.5, 1:1 and 1:1.5, respectively. For taste testing, the granules from the melt extrusion line were milled in a cooled laboratory mill and the powder fraction below 315 µm (which would be used in tablet production) taken for taste testing.

Taste testing of the powder was done according to the German Pharmacopeia of 1999 to measure the bitterness value (the reciprocal of the concentration at which the drug/extrudate suspension tastes only slightly unpleasant). When the three mixtures of EUDRAGIT® E 100 and ibuprofen were tested, both as milled extrudate and pelletized granules, only the molar ratio of 1:1.5 (excess ibuprofen) showed even a slightly unpleasant taste.

Thus, the bitterness value of ibuprofen was reduced by at least four powers of ten in all three batches, showing a high degree of taste masking (Figure 3).

This degree of taste masking is much higher than would be expected from just embedding the active substance in the polymer matrix, and supports the idea that ionic interactions are responsible. Ionic interaction can, however, be directly demonstrated, for example by infrared spectroscopy. Thus, when EUDRAGIT® E 100/ibuprofen extrudate was examined by IR spectroscopy, a clear absorption band due to carboxylate salt could be seen, as well as bands due to excess dimethylamino groups of the polymer and carboxyl groups of ibuprofen (Figure 4).

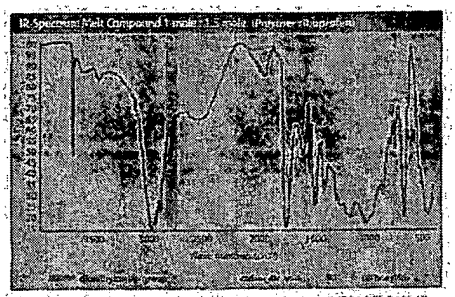

Figure 4. IR spectral signature of carboxylate ionic interaction in an EUDRAGIT® E 100 / ibuprofen extrudate

Further evidence of interaction was obtained by measuring the glass transition temperature of the substances, which was 50°C for pure EUDRAGIT® E 100 polymer, but decreased to 7°C for extrudate with a molar ratio of 1:1 EUDRAGIT® polymer to ibuprofen.

Ionic Interaction Is Reversible

The ionic interaction seen during melt extrusion is fully reversed as the formulation dissolves. This is important to ensure unhindered release of the active substance. In dissolution tests, complete release was observed in 10 minutes at pH 1.2 (simulating conditions in the stomach). Thus, having protected the mouth and upper gastrointestinal tract from an unpleasant taste, ionic interaction in the extrudate is fully reversed, releasing the active substance in the stomach, as desired.

Ionic interaction during melt extrusion between oppositely charged EUDRAGIT® polymer and active substance is more than a scientific curiosity. It can also help patients to "swallow the nasty medicine" and get it to where it can be absorbed, without leaving a bad taste in the mouth. ■

	Milled extrudate 2.7 mg/100 ml	Granulation 2.7 mg/100 ml	Granulation 0.1 mg/100 ml
Molar ratio Polymer/ibuprofen = 1:0.5	No unpleasant taste of ibuprofen	No unpleasant taste of ibuprofen	< 0.00007 mg/l
Molar ratio Polymer/ibuprofen = 1:1	No unpleasant taste of ibuprofen	No unpleasant taste of ibuprofen	< 0.00007 mg/l
Molar ratio Polymer/ibuprofen = 1:1.5	Short taste of ibuprofen (after 40 seconds)	No unpleasant taste of ibuprofen	< 0.00007 mg/l

Figure 3. Extruding ibuprofen with EUDRAGIT® E 100 provided highly effective taste masking.

Figure 5. Melt extrusion according to GMP guidelines

Glidants for EUDRAGIT® Polymer Coatings

Glyceryl Monostearate – a Novel "Anti-Tacking" Agent

Spray coating of pharmaceutical tablets with thin films of materials such as EUDRAGIT® polymers is a convenient and well-established method for protecting the active substance from atmospheric moisture and for controlling its release rate and site in the gastrointestinal tract. However, it is usually necessary to add an "anti-tacking" agent (glidant) to the polymer coating formulation to reduce the likelihood of sticking during coating.

The mineral talc (magnesium silicate hydrate) has been used in polymer coatings for this purpose for many years, with generally good results.

However, it is often necessary to use relatively large amounts of talc in proportion to the dry polymer to effectively prevent sticking. This can impair coating efficiency and polymer loading. It increases both the coating time and operating costs. Talc also has a relatively high sedimentation rate in low-viscosity coating solutions, which complicates the spraying process. An alternative is therefore required to avoid such problems.

Glyceryl monostearate (mono- and diglycerides NF) is one such alternative, which was described as a new glidant by Pharma Polymers scientists already in the 1990s.[1] It has been widely used as a food additive, as an emulsifier for oils, waxes and solvents, and in cosmetic, skin care and hair care products, as well as for its glidant properties in tablet coating.

Glyceryl monostearate of a grade suitable for pharmaceutical use can be derived both from animal sources or entirely from plant sources (coconut, soybean, palm etc).

Preparing an Aqueous Dispersion

Glyceryl monostearate is a hydrophobic, waxy substance with a low melting point (58-59°C) that is usually brought into aqueous suspension for mixing with other coating ingredients by homogenizing a warm emulsion, then adding a polysorbate detergent such as Tween® 80.

The newer, plant-derived GMS products have slightly different analytical properties from the older animal-based preparations. It was therefore desirable to check that no modification of the film coating procedure would be necessary when switching from one to the other.

To test this, three samples of GMS were studied:

- Imwitor® 900 (animal-based) and
- Imwitor® 900K (plant-derived) both from the Sasol company, Hamburg, Germany
- Geleol® (plant-derived), from the Gattefossé company, Weil-am-Rhein, Germany.

The best preparation method was found to involve homogenization of GMS together with triethyl citrate and Tween® 80 (40 wt-% on GMS) in hot water (min. 70°C) at a total solids concentration of 15-20%.

Mixing was performed in an Ultra Turrax at 4,000 rpm for 10 minutes, followed by dilution with cold water to a final solids concentration of ca. 6%, which reduced the temperature to below 40°C.

Particle Size Distribution

Investigation of the resulting suspension by laser diffractometry (Mastersizer 2000, version 4.00, Malvern Instruments Ltd) showed that a particle size distribution with a single peak was obtained with Imwitor® 900 and Geleol®, corresponding to mean particle sizes of ca. 3 µm and 10 µm respectively, while Imwitor® 900K showed a biphasic peak with maxima at ca. 0.25 µm and 6 µm (Figure 1.)

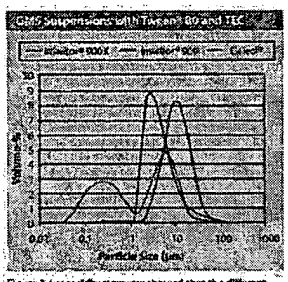

Figure 1. Laser diffractometry showed that the different GMS preparations provided differently sized dispersions on homogenization.

Another unexpected finding was the discovery that the particle size distribution of dispersions of Imwitor® 900K prepared in this way changes markedly over time, after being left to stand at room temperature (Figure 2).

The peak of very small particles (around 0.2 – 0.3 µm) seen in freshly prepared suspensions declines, while there is an increase in particles of about 10 µm diameter.

Eventually, after 48 hours standing, extra peaks are seen at particle sizes of 100 µm and larger, which can be interpreted as being due to a gradual aggregation of the GMS particles.

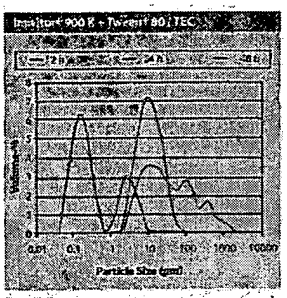

Figure 2. On storage at room temperature, suspensions of GMS showed a marked aggregation over time.

Film Coating Properties

The differences between GMS preparations in terms of average particle sizes and the aggregation of dispersed GMS particles over time were unexpected findings, but these turn out not to have any significant influence on the film coating process. Smooth, regular coating of good visual appearance was obtained with all three GMS preparations.

In trial experiments, suspensions of the three different preparations were mixed with EUDRAGIT® L 30 D-55 – a polymer often used for enteric coating – and used to coat placebo tablets. No quality differences were noted between the resulting coated tablets (Figure 3a, b, c). Smooth, homogeneous polymer coatings of approximately 50 µm thickness were obtained, without sticking problems during the coating process.

In separate pilot-scale experiments, paracetamol tablets were coated with EUDRAGIT® L30 D-55 using vegetable-derived GMS (Imwitor® 900K) as the glidant. Their appearance and dissolution properties were checked against control tablets made using talc as the glidant (5% w/w of dry polymer substance in each case).

Tablets coated using GMS as the glidant were found to be smooth, uniform and elegant in appearance and, like those made using talc, released no detectable active substance during 2 hours at pH 1.2, but dissolved completely within 40 minutes at pH 6.8, as required by USP specifications. Thus, GMS from vegetable sources is a fully satisfactory alternative glidant to conventional talc and is easily incorporated into standard tablet coating procedures.

These investigations of the use of GMS as a glidant in tablet coating are an example of the commitment of Pharma Polymers scientists to help clients optimize their product development processes. To help you take advantage of our many years of experience, Pharma Polymers has established Technical Service Centers throughout the world to provide customer support.

We hope you will take advantage of these facilities and look forward to working together with you. ■

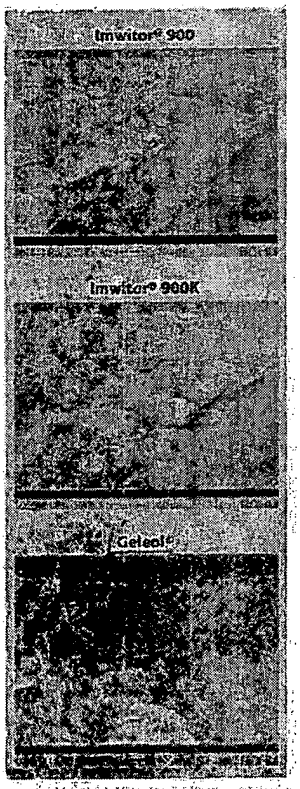

Figure 3. Scanning electron micrographs of placebo tablets coated with EUDRAGIT® L 30 D-55 (5 mg polymer/cm²), using the GMS preparations (a) Imwitor® 900, (b) Imwitor® 900K and (c) Geleol®. The quantity of GMS used was 5% w/w of dry polymer substance in each case.

Component	Amount	Dry weight	Dry polymer
EUDRAGIT® L 30 D-55	12.12 g	3.70 g	
Triethyl citrate	0.37 g	0.37 g	10%
Imwitor® 900K	3.19 g	3.19 g	5%
Tween® 80	1.27 g	1.27 g	2%
Titanium dioxide	1.91 g	1.91 g	3%
FD&C Yellow Lake	1.27 g	1.27 g	2%
Water	76.40 g		
Total	100.53 g	77.71 g	22% w/w solids

Table 1: Specimen formulation for tablet coating with a colored polymer film, using Imwitor® 900K as the glidant.

References

- Glyceryl monostearate as a glidant in aqueous film-coating formulations. Eur. J. Pharm. Biopharm. 1995; 41(4): 219-228. Petereit HU, Assmus M, Klaus L.
- Glyceryl monostearate as a glidant in color coated tablets with EUDRAGIT® L30 D-55: Effect on tablet surface morphology. AAPS Pharm. Sci. 2003; 5(4): Abstract T3297. Annamalai M, Gaiperina K, Bradley R, Mehta KA. Presented at AAPS meeting, Salt Lake City, 26-30 Oct 2003.

Pharma Polymers Business Line Organization Expanded in Darmstadt, Piscataway and Tokyo

New Staff and New Staffing

Darmstadt

New at the Pharma Polymers team are Dr. Randy Bull, Thomas Fürst and Jonas Ide.

Dr. Randy Bull
was promoted to Global Business Director of EUDRAGIT® in March 2004, having worldwide responsibility for marketing and field sales organizations. In the past four years, he was in charge of commercial operations, including sales, marketing, business development and product logistics for the U.S. Business Line. His industry experience spans many functions, including R&D, business development, marketing and sales management. Randy Bull earned his BS degree in Chemistry from Lebanon Valley College, and received his PhD in Inorganic Chemistry from the University of Delaware.

Thomas Fürst
has been working in the Technical Customer Service for EUDRAGIT® since March 2004. His duties also include the technical supervision of customer projects to develop new pharmaceutical dosage forms and clinical test preparations. Thomas Fürst earned his Master's degree in Pharmaceutics at the University of Frankfurt, where he was employed for four years as a scientific assistant at the Institute for Pharmaceutical Technology.

Jonas Ide
took over product management of EUDRAGIT® in October 2004. Prior to that, during his studies at the University of Cooperative Education in Mannheim in cooperation with Röhm GmbH & Co. KG, he did several internships in sales and marketing at the Pharma Polymers Business Line and at Rohm America in Piscataway. Jonas Ide completed his studies in business administration in Mannheim (Diplom-Betriebswirt BA), having majored in marketing, finance and accounting.


New at the Pharma Polymers team in Darmstadt (l. t. r.): Thomas Fürst, Jonas Ide, Dr. Randy Bull

Regulatory News

New Ph. Eur. Monographs for EUDRAGIT® RL 100/ RL PO and RS 100/ RS PO

The monographs for "Ammonio Methacrylate Copolymer (Type A and Type B)" have been included in the European Pharmacopoeia Ph. Eur. 4.7. They have been in force since **April 1, 2004**. That means these polymers are now described in the three internationally accepted compendia of pharmaceutical excipients, USP/NF, JPE and Ph. Eur.

New USP/NF Monographs for EUDRAGIT® RL 30 D and RS 30 D

The monograph for "Ammonio Methacrylate Copolymer Dispersion (Type A and Type B)" has been published in USP27/NF 22 Supplement 2. It has been in force since **August 1, 2004**. That means the aqueous EUDRAGIT® RL 30 D and EUDRAGIT® RS 30 dispersions are now also described for the first time in a pharmacopeia.


Supporting the U.S. Pharma Polymers team (l. t. r.): Dr. Nasser Nyamweya, Thomas Mallon and Dr. Ketan Mehta


New staff at Pharma Polymers in Japan (l. t. r.): Masami Kato, Takayuki Morita, Kenji Hama

Piscataway

The Rohm Pharma Polymers team is supported by Dr. Ketan Mehta, Nasser Nyamweya and Thomas Mallon.

Dr. Ketan Mehta
was appointed U.S. Regional Business Manager in February 2004 and is now responsible for commercial business operations, including sales, marketing, business development and product logistics. In addition, he coordinates the technical service, of which he was the previous manager. Ketan Mehta earned his BS in Pharmacy from Poona University, India; his PhD in Pharmaceutical Sciences from the University of Rhode Island; and his MBA in marketing from Rutgers, the State University of New Jersey.

Dr. Nasser Nyamweya
took over the position of U.S. Technical Manager EUDRAGIT® in May 2004 and coordinates the technical activities of the laboratory with three staff members. His former pharmaceutical experience includes R&D and product development. Nasser Nyamweya earned his BS in Biology at Spring Arbor College, MI, followed by a Master's degree in Pharmaceutical Sciences from the University of Arkansas, and a Ph.D. in Pharmaceutical Sciences from the University of Maryland School of Pharmacy.

Thomas Mallon
joined Rohm Pharma Polymers and Rohm Specialty Acrylics as a U.S. Key Account Manager in February 2004. His responsibilities include key account management for select multinational pharmaceutical companies, with particular focus on companies headquartered in the USA, and for key regional accounts located in the mid-west. Before joining Degussa, Thomas Mallon worked at MEECO Inc. as Executive Vice President of Worldwide Sales. He holds an MBA in Finance from St. Joseph's University.

Tokyo

As of April 1, 2004, Pharma Polymers has become established with its EUDRAGIT® brand in Japan, with headquarters in Tokyo and offices in Osaka, as well as two warehouses. In October 2004, the Technical Service Laboratory was installed at Tsukuba Plant & Research Center, headed by Takayuki Morita.

Masami Kato
joined Pharma Polymers in April 2004 as Marketing Manager for the Tokyo area. For the last 11 years, he was involved in EUDRAGIT® business at Higuchi Inc. In his new position, he utilizes his experience and knowledge of EUDRAGIT® to expand business in Japan. He studied commerce & marketing at the University of Kanagawa and earned a Bachelor of Economics.

Kenji Hama
became a member of the sales team at the Osaka office in May 2004. Prior to joining Degussa, he worked for 13 years as an engineer in various branches of industry, especially pharmaceuticals. Most recently, in his former company Kawata MFG. Co. Ltd., his job as an engineer included feasibility studies on pharmaceutical products and marketing. He studied industrial chemistry at the University of Tottori and earned a Bachelor of Industrial Chemistry.

Takayuki Morita
joined the Technical Service department in Japan in January 2004. In his previous position, he was employed as a process engineer at Bayer Yakuhin, Ltd., and before that worked as an assessment engineer at the Japanese machinery company Powrex Cooperation. Takayuki Morita studied chemical engineering at Osaka Prefecture University. ■

CREDITS
Published by: Röhm GmbH & Co. KG Pharma Polymers · 64275 Darmstadt · Germany
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Photos: Röhm GmbH & Co. KG
Layout: Profilwerkstatt Darmstadt · Printed by: DMR Druck und Medien Realisation GmbH, Griesheim
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Hydrine

hibitor; surfactant

Aqualox® 236 [Gateway Addit.] Amine carboxylate; lubricant, corrosion inhibitor

Aqualox® 240 [Gateway Addit.] Amine carboxylate; surfactant, corrosion inhibitor

Aqualox® 242HT-90 [Gateway Addit.] Amine salt of org. acids; corrosion inhibitor, hydrotrope

Aqualox® 2268 [Gateway Addit.] Corrosion inhibitor, lubricant

Aqualox® 2295 [Gateway Addit.] Rust preventive conc.

Aqualox® 2320 [Gateway Addit.] Corrosion inhibitor, lubricant

Aqualox® 2328 [Gateway Addit.] Corrosion inhibitor, lubricant

Aqualox® 2500 [Gateway Addit.] Corrosion inhibitor, emulsifier

Becrosan® 2128A [Gateway Addit.] Arylsulfonamido carboxylic acid; corrosion inhibitor intermediate

Bio-Base GT-9000 [Gateway Addit.] Sodium sulfonate, branch chained sat. ester as sec. emulsifier, emulsifier base, antimicrobial, corrosion inhibitor, lubricant

Bio-Base GT-9001 [Gateway Addit.] Borated sodium sulfonate, branch chained sat. ester as sec. emulsifier, emulsifier, lubricant, dispersant

Olicat® C [Gateway Addit.] Polyisobutylene in mineral oil; tackiness agent, lubricant

Semi-Synthetic Base 2550 [Gateway Addit.] Base, lubricant, corrosion inhibitor, wetting agent

Semi-Synthetic Base 2590 [Gateway Addit.] Base, lubricant, corrosion inhibitor, wetting agent

Soluble Base GT-1150 [Gateway Addit.] Mixt. of high m.w. sodium sulfonate, sec. emulsifier system, and coupling agents; emulsifier base, lubricant, corrosion inhibitor

Soluble Base GT-1500 [Gateway Addit.] Mixt. of sodium sulfonate, sec. emulsifier; emulsifier base, lubricant, corrosion inhibitor

Soluble Base GT-1700VN [Gateway Addit.] Mixt. of sodium sulfonate, sec. emulsifier system, and coupling agents; emulsifier base, corrosion inhibitor

Soluble Base GT-1700VP [Gateway Addit.] Mixt. of sodium sulfonate, sec. emulsifier system, and coupling agents; emulsifier base, corrosion inhibitor

Syn-Ester® GY-10 [Gateway Addit.] High m.w. polymerized ester; lubricant, EP agent

Syn-Ester® GY-15 [Gateway Addit.] High m.w. polymerized ester; lubricant, EP agent

Syn-Ester® GY-16 [Gateway Addit.] Syn. high m.w. polymerized ester; sec. emulsifier

Syn-Ester® GY-25 [Gateway Addit.] High m.w. polymerized ester; lubricant, EP agent

Syn-Ester® GY-35 [Gateway Addit.] Syn. polymerized ester; sec. emulsifier

Syn-Ester® GY-201 [Gateway Addit.] High m.w. syn. branched chain saturated ester; EP agent, lubricant, corrosion inhibitor

Syn-Ester® GY-301 [Gateway Addit.] Syn. ester; coemulsifier; wetting agent

Syn-Ester® GY-500 [Gateway Addit.] Polymerized ester; lubricant, visc. index improver

Syn-Ester® GY-HTO [Gateway Addit.] High m.w. polymerized ester; EP agent, lubricant, corrosion inhibitor

Syn-Ester® SE-110 [Gateway Addit.] Sulfurized polymerized ester; lubricant, EP agent

Syn-Ester® SE-115 [Gateway Addit.] Sulfurized polymerized ester; lubricant, EP agent

Syn-Ester® SE-120 [Gateway Addit.] Sulfurized polymerized ester; lubricant, EP agent

Synthetic Micro-Emulsion ST-3100 [Gateway Addit.] Water-extendible base; lubricant

Gattefossé

Gattefossé S.A., 36 Chemin de Genas, BP 603, 69804 Saint Priest, Cedex, France (Tel: 33 4 72 22 98 00; FAX 33 4 78 90 45 67; Internet: www.gattefosse.com)

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Gattefossé A.G., Haldenstrasse 11, 6006 Luzern, Switzerland (Tel: 41 41 410 49 66; FAX 41 41 410 35 53)

Gattefosse (UK) Ltd., Arc House, Terrace Rd. South, Binfield, Bracknell, Berkshire, RG42 4PZ, UK (Tel: 44 1344 86 18 00; FAX 44 1344 45 14 00)

Gattefossé Italia s.r.l., Via Derganino 20, 20158 Milan, Italy (Tel: 39 2 39 31 40 73; FAX 39 2 66 200 440; E-mail: cperego@gattefosse.it)

Gattefossé España, S.A., Avda. Diagonal 460, 6°A, 08006 Barcelona, Spain (Tel: 34 93 416 05 20; FAX 34 93 415 35 46)

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Gattefosse Canada, Inc., 711 Devon Pl., Baie d'Urfe, Quebec, H9X 2T3, Canada (Tel: 514-457-0921; FAX 514-457-0922; E-mail: jasminep@gattefosseca.com)

Gattefossé Korea, # 1403 Sung Ji Heights III 642-6, Yuksamdong, Kangnamgu, Seoul, 135-080, Korea (Tel: 82 2 508 3877; FAX 82 2 568 0425)

Trade Names:

Antistatique WL 879 [Gattefosse] Sorbitan caprylate; antistat

Apifil® [Gattefosse; Gattefosse SA] PEG-8 beeswax; emulsifier, moisturizer

Atowax [Gattefosse] Atomized beeswax; excipient, polishing agent, emulsion stabilizer, stiffening agent

Brillance 515 [Gattefosse] Apricot kernel oil PEG-6 esters and ethylcellulose; cosmetic ingred.

Capryol® PGMC [Gattefosse SA] Propylene glycol monocaprylate; CAS 31565-12-5; solubilizer

Cetasal [Gattefosse] Propylene glycol stearate, stearic acid, TEA-stearate, sulfated castor oil; gelifying, self-emulsifying base for o/w creams

Compricoat [Gattefosse] PEG-20 behenate; excipient, coating agent, emulsifier, solubilizer, wetting agent

Compritol 888 [Gattefosse; Gattefosse SA] Tribehenin; CAS 18641-57-1; excipient, lubricant

Compritol® 888 ATO [Gattefosse; Gattefosse SA] Tribehenin; CAS 18641-57-1; food emulsifier, excipient, lubricant, binder

Compritol HD5 ATO [Gattefosse; Gattefosse SA] PEG-8 behenate and tribehenin; excipient, lubricant, viscosifier, stiffening and brightening agent

D.P.P.G. [Gattefosse SA] Propylene glycol dipelargonate; CAS 41395-83-9; emollient

Emulcire 61 [Gattefosse; Gattefosse SA] Cetyl alcohol, ceteth-20, and steareth-20; self-emulsifying base

Emulium® Delta [Gattefosse] Cetyl alcohol, glyceryl stearate, PEG-75 stearate, ceteth-20, steareth-20; emulsifier

Fondix G Bis [Gattefosse SA] Propylene glycol, sodium methylparaben, sodium dehydroacetate, sorbic acid, tetrasodium EDTA; cosmetic preservative

Gatuline® A [Gattefosse SA] Pilewort (Ranunculus ficaria) extract; CAS 84929-74-8; skin treatment

Geleol® [Gattefosse; Gattefosse SA] Glyceryl stearate; CAS 31566-31-1; emulsifier, opacifier, excipient

Gelot 64® [Gattefosse; Gattefosse SA] Glyceryl stearate and PEG-75 stearate; self-emulsifying cosmetic/pharmaceutical base; excipient

Gelucire 33/01 [Gattefosse SA] Glycerol esters of sat. C8-C18 fatty acids USP/NF; excipient, carrier, vehicle, antioxidant

Gelucire 37/02 [Gattefosse SA] Saturated polyglycolized glycerides; excipient

Gelucire 39/01 [Gattefosse] Glycerol esters of sat. C12-C18 fatty acids; excipient, vehicle, consistency agent, fatting agent, antioxidant

Gelucire 43/01 [Gattefosse] Glycerol esters of sat. C12-C18 fatty acids; excipient, vehicle, consistency fatting agent

Gelucire 44/14 [Gattefosse SA] PEG-32 glyceryl laurate EP; excipient, solubilizer, emulsifier

Gelucire 50/02 [Gattefosse SA] Saturated polyglycolized glycerides; excipient

Gelucire 50/13 [Gattefosse SA] PEG-32 glyceryl palmitostearate; excipient

Gelucire 53/10 [Gattefosse SA] PEG-32 glyceryl stearate; excipient

Hydrine® [Gattefosse; Gattefosse SA] PEG-2 stearate; CAS 9004-99-3; thickener, gellant, stabilizer

Hydrolactol 70 [Gattefosse; Gattefosse SA] Glyceryl stearate, propylene glycol stearate, glyceryl isostearate, propylene glycol isostearate, oleth-

Monthyle

Printed from: *Pharmaceutical Excipients*. London: Pharmaceutical Press. Electronic version, 2007.

Ethylene Glycol Palmitostearate

1. Nonproprietary Names

BP: Ethylene glycol monopalmitostearate
PhEur: Ethyleneglycoli monopalmitostearas

2. Synonyms

—

3. Chemical Name and CAS Registry Number

Ethylene glycol palmitostearate

See Sections 8 and 17.

4. Empirical Formula and Molecular Weight

See Section 8.

5. Structural Formula

See Section 8.

6. Functional Category

Emollient; emulsifying agent; stabilizing agent.

7. Applications in Pharmaceutical Formulation or Technology

Ethylene glycol palmitostearate is used as a stabilizer for water-in-oil emulsions, although it has poor emulsifying properties. It has emollient properties and is also used as an opacifying, thickening, and dispersing agent.

In cosmetics, ethylene glycol palmitostearate is used as a 'fatty body' for lipsticks, as a pearling agent in opalescent and cream shampoos, and as an additive for tanning lubricants.

8. Description

The PhEur 2005 describes ethylene glycol palmitostearate as a mixture of ethylene glycol monoesters and diesters of stearic and palmitic acids, produced from the condensation of ethylene glycol and stearic acid 50, of vegetable or animal origin.

Ethylene glycol palmitostearate occurs as a white or almost white waxy solid.

9. Pharmacopeial Specifications

See Table I.

10. Typical Properties

Melting point: 54–60°C

Solubility: soluble in acetone and hot ethanol (95%); practically insoluble in water.

11. Stability and Storage Conditions

Ethylene glycol palmitostearate should be stored in a cool, dark place, protected from light.

12. Incompatibilities

—

13. Method of Manufacture

Ethylene glycol palmitostearate is produced from the condensation of ethylene glycol with stearic acid 50 of vegetable or animal origin.

14. Safety

Ethylene glycol palmitostearate is mainly used in cosmetics and topical pharmaceutical formulations, where it is generally regarded as a relatively nontoxic and nonirritant material.

15. Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16. Regulatory Status

Included in nonparenteral medicines licensed in Europe.

17. Related Substances

Diethylene glycol monopalmitostearate; ethylene glycol monopalmitate; ethylene glycol monostearate; glyceryl monostearate; glyceryl palmitostearate.

Diethylene glycol monopalmitostearate

Synonyms: diethyleneglycoli monopalmitostearas; diethylene glycol palmitostearate.

Description: the PhEur 2005 describes diethylene glycol monopalmitostearate as a mixture of diethylene glycol monoesters and diesters of stearic and palmitic acids. It contains not less than 45.0% of monoesters produced from the condensation of diethylene glycol and stearic acid 50 of vegetable or animal origin. Diethylene glycol monopalmitostearate occurs as a white or almost white waxy solid.

Acid value: ≤4.0

Iodine value: ≤3.0

Melting point: 43–50°C

Saponification value: 150–170

Solubility: soluble in acetone and hot ethanol (95%); practically insoluble in water.

Ethylene glycol monopalmitate

CAS number: [4219-49-2]

Ethylene glycol monostearate

Synonyms: ethylene glycol stearate; ethylene glycoli monostearas; ethyleni glycoli stearas; 2-hydroxyethyl ester stearic acid; *Monestriol EN-A*; ***Monthyle***.

CAS number: [111-60-4]

Empirical formula: $C_{20}H_{40}O_3$

Molecular weight: 328.60

Description: occurs as pale yellow flakes.

Melting point: 57–63°C

Safety:

LD_{50} (mouse, IP): 0.20 g/kg[1]

18. Comments

—

19. Specific References

1. Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 11th edn. New York: Wiley, 2004: 1669.

20. General References

Sweetman S, ed. *Martindale: The Complete Drug Reference*. 34th edn. London: Pharmaceutical Press, 2005: 1411.

21. Authors

SC Owen, PJ Sheskey.

22. Date of Revision

12 August 2005.

Chemical Database

2-Hydroxyethyl Octadecanoate

Identifications

- **CAS Number:** 111-60-4
- **CAS Number:** 9004-99-3
- **Synonyms/Related:**
  - 17-Hydroxy-3,6,9,12,15-pentaoxaheptadec-1-yl octadecanoate
  - 2-Hydroxyethyl Octadecanoate
  - 2-Hydroxyethyl stearate
  - 26-Hydroxy-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl octadecanoate
  - 40S
  - 41-Hydroxy-3,6,9,12,15,18,21,24,-27,30,33,36,39-tridecaoxahentetr- acont-1-yl octadecanoate
  - 60S
  - Akyporox S 100
  - alpha-(1-Oxooctadecyl)-omega-hydroxypoly(oxy-1,2-ethanediyl)
  - Arosurf 1855E40
  - C12998
  - Carbowax 1000 monostearate
  - Carbowax 4000 monostearate
  - Cerasynt 660
  - Cerasynt M
  - Cerasynt MN
  - Cithrol 10MS
  - Cithrol PS
  - Clearate G
  - Clindrol SEG
  - Cremophor A
  - Crill 20,21,22, 23
  - Crill 20,21,22,23
  - D01542
  - EM
  - Emanon 3113
  - Emanon 3199
  - Emcol H 35-A
  - Emerest 2350
  - Emerest 2640
  - Emersal
  - Emersal (TN)
  - Emery 15393
  - Empilan 2848
  - Empilan CP-100
  - Empilan CQ-100

- Emulphor VT-650
- Emunon 3115
- Ethofat 60/15
- Ethofat 60/20
- Ethofat 60/25
- Ethoxylated stearic acid
- Ethylene glycol monostearate
- Ethylene glycol monostearate SE
- Ethylene glycol stearate
- Ethylene glycol, monostearate
- Glycol monostearate
- Glycol monostearate SE
- Glycol polyethylene monostearate #200
- Glycol stearate
- Glycol stearate SE
- Glycol, polyethylene monostearate #200
- Glycol, polyethylene monostearate #6000
- Glycols, polyethylene, monostearate
- Ionet MS-1000
- Ivorit
- Kessco X-211
- Lactine
- Lamacit CA
- Lipal 15S
- Lipal 400-S
- Lipo EGMS
- Lipo-Peg 4-S
- LX 3
- Macrogol stearate 2000
- Magi 45
- Monthybase
- Monthyle
- Myrj
- Myrj 45
- MYRJ 49
- Myrj 51
- MYRJ 52
- Myrj 52S
- Myrj 53
- Myrj 59
- Myrj solution
- MYS 40
- MYS 45
- Nikkol MYS
- Nikkol MYS 4
- Nikkol MYS 40
- Nikkol MYS 45
- Nikkol MYS-25

- Nissan Nonion S 15
- Nissan Nonion S-2
- Nonex 28
- Nonex 29
- Nonex 36
- Nonex 53
- Nonex 54
- Nonex 63
- Nonion S 15
- Nonion S 2
- Nonion S 4
- Octadecanoic acid, 17-hydroxy-3,6,9,12,15-pentaoxaheptadec-1-yl ester
- OCTADECANOIC ACID, 2-HYDROXYETHYL ESTER
- Octadecanoic acid, 26-hydroxy-3,6,9,12,15,18,21,24-octaoxahexacos-1-yl ester
- Octadecanoic acid, 41-hydroxy-3,6,9,12,15,18,21,24,27,30,33,36,39-tridecaoxahentetra- cont-1-yl ester
- Parastarin
- PEG 1000MS
- PEG 100MS
- PEG 42
- PEG 600MS
- PEG stearate
- PEG-10 Stearate
- PEG-150 stearate
- PEG-40 stearate
- PEG-8 Stearate
- Pegosperse S 9
- Perphinol 45/100
- PMS No. 1
- PMS No. 2
- Poly (oxy-1,2-ethanediyl) , .alpha.-(1-oxooctadecyl)-.omega.-hydroxy-
- Poly(oxy-1, 2-ethanediyl) , .alpha.-hydro-.omega.-hydroxy-, octadecanoate
- Poly(oxy-1,2-ethanediyl) , .alpha.-(1-oxooctadecyl)-.omega.-hydroxy-
- Poly(oxy-1,2-ethanediyl) , alpha-(1-oxooctadecyl)-omega-hydroxy-
- Poly(oxy-1,2-ethanediyl) , alpha-1-(oxooctadecyl)-omega-hydroxy-
- Poly(oxy-1,2-ethanediyl) , alpha-hydro-omega-hydroxy-, octadecanoate
- Poly(oxyethylene) monostearate
- Poly(oxyethylene) stearate
- Poly(oxyethylene) stearic acid ester
- Polyethylene glycol (100) monostearate
- Polyethylene glycol 8 monostearate
- Polyethylene glycol monostearate
- Polyethylene glycol monostearate #1000
- Polyethylene glycol monostearate #200
- Polyethylene glycol monostearate #40
- Polyethylene glycol monostearate #400
- Polyethylene glycol monostearate #6000
- Polyethylene glycol stearate

- Polyethylene oxide monostearate
- Polyethylene oxide stearate
- Polyethyleneglycols monostearate
- Polyethyleneglycols monstearate
- Polyoxyethylate (9) stearic acid
- Polyoxyethylene (8) stearate
- Polyoxyethylene 50 stearate
- Polyoxyethylene monostearate
- Polyoxyethylene stearate (mol. wt. 600-2000)
- Polyoxyethylene(8) stearate
- Polyoxyethylene-(40)-monostearate
- Polyoxyethylene-8-monostearate
- Polyoxyl 40 stearate
- Polyoxyl 40 stearate (JP14/NF)
- Polyoxyl 40 stearate [USAN:BAN:JAN]
- Polyoxyl 50 stearate
- Polyoxyl 8 stearate
- Polyoxyl 8 stearate [USAN:BAN]
- Polystate
- Polystate B
- Prodhybas N
- Prodhybase 4000
- Prodhybase ethyl
- Prodhybase P
- S 1004
- S 1012
- S 1016
- S 1042
- S 1054
- S 1116
- S 151
- S 541
- Sedetol
- Slovasol MKS 16
- Soromin-SG
- Stabilisant delta.-118
- Stabilisant delta-118
- STEARIC ACID, 2-HYDROXYETHYL ESTER
- Stearic acid, monoester with ethylene glycol
- Stearic acid, monoester with polyethylene glycol
- Stearoks 6
- Stearoks 920
- Stearox 6
- Stearox 920
- Stearoxa-6
- Stenol 8
- Tegin G
- Tego-stearate

- Trydet SA 40
- Trydet SA series
- USAF KE-11
- Usaf ke-12
- Usaf ke-14
- Usaf ke-9
- X-489-R

Related Resources

- **USDOT Hazardous Materials Table 49 CFR 172.101**
  An online version of the USDOT's listing of hazardous materials from 49CFR 172.101. This table can be sorted by proper shipping name, UN/NA ID and/or by primary hazard class/division.
- **2004 ERG (Emergency Response Guidebook)**
  Have you ever wondered what those four digit numbers on the placards on the side of trucks and rail cars mean? Our online 2004ERG will give you your answer. This is an online version of the guidebook produced by the USDOT for first responders during the initial phase of a Dangerous goods/HazMat incident.
- **US DOT Hazardous Materials Transportation Placards**
  Hazardous materials placards (DOT placards) are required when shipping hazardous materials in the United States, Canada and Mexico. These pages provide US DOT definitions for each hazmat placard.
- **Guide for Handling Household Chemicals**
  Things you can do to make your home safer.
- **Molarity, Molality and Normality**
  Introduces stoichiometry and explains the differences between molarity, molality and normality.
- **Molar Mass Calculations and Javascript Calculator**
  Molar mass calculations are explained and there is a JavaScript calculator to aid calculations.
- **Periodic Table of Elements**
  Provides comprehensive data for each element of the periodic table of elements including up to 40 properties, names in 10 languages and common chemical compounds. Information also provided for 3,600 nuclides and 4,400 nuclide decay modes.

Editor's note: Some chemicals in this database contain more information than others due to the original reason this information was collected and how the compilation was accomplished.

While working with material safety data sheets (MSDS), I found that manufacturers sometimes used obscure names for constituent chemicals and I didn't always have a good idea of what I was dealing with. To resolve this problem, over the years, I compiled chemical names and identifiers into a personal database, cross referencing regulatory and health safety information when possible. Colleagues and friends eventually started suggesting that I make my data available on this website so that others could benefit from my efforts -- which I finally did in 2004. The more common, regulated and/or hazardous a chemical is, the more information I will have likely collected it.

Further notes are below.

so that trademarks can be appropriately noted.

Notes about mixtures

Some chemicals listed in this database or not pure chemical compounds, rather they are mixtures/solutions of chemicals. It is not uncommon for wide range of molar ratios of a mixture to be lumped together as "synonyms" of the same "chemical". In some instances chemicals that are very similar from a health & safety and/or regulatory standpoint also may have been lumped together.

Reference Sources

Data for this database was compiled from: hundreds of Material Safety Data Sheets (MSDS) of common industrial and household products; the Hazardous Materials Table from the United States "Code of Federal Regulations" title 49 section 172.101; the National Institute for Occupational Safety and Health Pocket Guide to Chemical Hazards; the US DOT 1996, 2000 & 2004 Emergency Response Guidebooks; U.S. National Library of Medicine and many other related resources.

Disclaimer

WARNING: These pages are for general reference and educational purposes only and MUST NOT be relied upon as a sole source to determine regulatory compliance or where matters of life and health are concerned. This site and the author do not warrant or guarantee the accuracy or the sufficiency of the information provided and do not assume any responsibility for its use.

To ensure regulatory compliance when transporting hazardous materials or dangerous goods, one must receive proper training and certification from a qualified instructor and refer to the current year's Code of Federal Regulations Title 49 (49CFR) or your country's shipping regulations. In matters regarding workplace safety, refer to current OSHA regulations (29CFR) and NIOSH guidelines or your own country's health and safety regulations. No one should ever enter into a hazardous environment without proper training from qualified instructors.

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